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Right to make changes to this operating manual are reserved.

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1 Introduction

1.1 Foreword

Dear User,

You have the task of using **PRIMEDIC™ DefiMonitor** to help a patient in a medical emergency!

In such a situation, you have to react quickly and correctly and use the functions offered by this device optimally. Therefore, it is important that you read this operating manual fully and thoroughly so that you are familiar with the device, its functions and its various applications.

Please keep this operating manual near the device for future reference!

Contact us for any queries on the device or other PRIMEDIC™ products.

Our contact details are given on the first page of this operating manual.

1.2 Scope

The information in this operating manual refers to all models of the

DefiMonitor XD

of **METRAX GmbH.**

Kindly note that the device, depending on the configuration, might not offer all features described in this manual.

1.3 Guarantee

METRAX GmbH offers a guarantee of 24 months on PRIMEDIC**™ DefiMonitor** starting from the date of purchase. Please make sure to keep the invoice verifying purchase of the device and respective date.

The general terms and conditions for guarantee and warranty of **METRAX GmbH** will apply.

Any repairs or modifications to the device can be carried out only by the manufacturer or any person or company authorised by the manufacturer.

1.4 Liability Exemptions

The company is excluded from all liability arising out of personal or material damage caused due to:

- Use other than for the purpose intended.
- Improper operation and servicing of the device.
- Operation without the protective covers or obvious damage to the cable and / or electrodes.
- Non-compliance of the instructions given in this operating manual with respect to the operation, servicing and repairs of the device.
- Use of accessories and spare parts manufactured by other companies.
- Unauthorised interventions, repairs or structural changes to the device.
- Exceeding the authorised performance limits
- Deficient monitoring of parts subject to wear and tear.
- Treatment of patients without any prior indications.

1.5 Symbols In This Operating Manual

Texts marked with this symbol contain very important instructions including instructions to prevent any health risks.
These instructions must be followed without fail!

Texts marked with the word GEFAHR (DANGER) warn against a very high degree of current risk, which, in the absence of precautions, will definitely cause severe injuries or will even result in death!
These instructions must be followed without fail!

Texts marked with the word WARNUNG (WARNING) warn against a very high degree of possible risk, which, in the absence of precautions, could cause severe injuries or could even result in death!
These instructions must be followed without fail!

Texts marked with the word VORSICHT (CAUTION) warn against a possibly dangerous situation that could lead to minor injuries or material damage!
These instructions must be followed without fail!

This symbol indicates texts containing important instructions / comments or tips.

● This dot describes processes to be carried out by you.

– This dash indicates lists.

(3) Numbers in brackets refer to items in illustrations.

< ... > Texts put in angle brackets are voice prompts / instructions from the device.

In case of the DefiMonitor model, the instructions are simultaneously displayed on the monitor.

1.6 Symbols On The Device

IP33 Protection against foreign objects > 2.5 mm
Protection against splashed water (60° to vertical)

Please follow the instructions in the operating manual!

Do not dump the device in your regular trash.

Safety level CF, opening is protected against defibrillation

Dangerous electric voltage (high voltage)

Safety level CF in conjunction with an ECG patient cable

1.7 Symbols On The SavePads

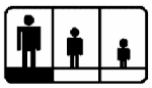
Not reusable

Expiry date

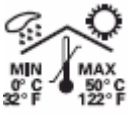
Lot number

Serial number

Manufacturing date


Only for adults

Item number



Storage temperature in Celsius and Fahrenheit

2 Intended Use

The DefiMonitor XD is intended for use by properly trained first responders, trained emergency medical technicians and physicians in daily clinical situations as well as in clinics in the pre-clinic area of emergency medicine and can be powered either by a chargeable, removable energy module or by the power mains. The compact and light construction makes it possible to bring along the DefiMonitor when a patient is transported. In the maximum version, the DefiMonitor consists of a defibrillator, EKG, external pacemaker, data recorder, pulsoximetry and printer.

The device is used to perform trans-thoraxal defibrillations. The main application is defibrillation in asynchronous manual mode, an additional application is the cardio version of atrial flutters in synchronous, manual mode. The decision on the necessity to provide a shock can either be by the user in automatic mode and automated by shock recommendation by the divide in AED mode.

When in automated mode, the energy levels of the initial, second and third shock with maximum current nominal values of 20A, 25A and 30A as well as the capacitor voltage dependant on the patient impedance are provided by default. In manual mode, it is possible to select the energy levels of 5-360J in order to facilitate a weight-adequate setting of the defibrillation energy according to the experiences of the physician. Thus, the defibrillation of children is possible with the appropriate electrodes in manual mode.

In addition, the device can be used to record and display electrocardiograms. The defibrillation electrodes are derived from the Einthoven II derivation in proper use. If an EKG cable is used instead of the defibrillation electrodes and commercial EKG electrodes, dual-channel monitoring is possible. Here any (logical) selection of 2 signals from the Einthoven I, II, III or Goldberger aVR, aVL, aVF – analog derivations can be shown. The prerequisite for this is correct positioning.

A printer is used to document the current EKG curves before and, if necessary, after defibrillation for purposes and issues arising as part of emergency application.

The device is intended for portable as well as stationary use and for **frequent** transport in civilian vehicles, particularly ambulances, outside, inside of buildings.

Any other use that is beyond the scope of such use shall be deemed as improper and can lead to personal or material damage!

PRIMEDIC™ DefiMonitor XD must only be used under conditions described in this operating manual and only in the manner described!

2.1 Indications/Contraindications of Defibrillation

The **PRIMEDIC™ DefiMonitor XD** shall ony be used, if atrial flutters/ fibrillations or certain arterial and ventrical tachycardial rhythm disorders exist which are accompanied by the following symptoms (indication):

- Unconscious and
- is not breathing and
- has no pulse or other signs of circulations.

The Defibrillator shall not be used, if the patient is

- is conscious or
- is breathing or
- has a detectable pulse or other signs of circulations or
- Asystoly
- Pulseless electrical activity
- Only applicable for automatic mode: a child under 8 years or less than 25 kg weight. (Per AHA Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, I-64, 2000).

2.2 Indications of Complications

1. Skin irritations to burns, e.g. not enough defibrillation gel was used
2. Any resulting myocardial damage due to the defibrillation energy
3.
4. Under some circumstances cardial rhythm disorders (e.g. atrial flutter or atrial fibrillation) after successful fibrillation or cardio version.

2.3 User Group

The DefiMonitor may only be used by specially trained medical personnel in manual mode.

In automatic mode, the DefiMonitor can be used by trained medical personnel. Use must be prescribed by a physician.

Improper use of the defibrillator can result in atrial flutter, Asystoly or other dangerous rhythmic disorders.

The operator of the DefiMonitor must ensure that the DefiMonitor is only used by authorised specialised personnel.

3 Safety Instructions

3.1 General Instructions

The **PRIMEDIC™ DefiMonitor XD** defibrillator and its standard as well as optional accessories fulfil all safety norms currently valid and meet all the criteria of the guidelines for medical devices.

The device and its accessories are safe if they are used for the purpose intended as described and instructed in this manual.

Nevertheless, the device and its accessories and their incorrect use can be dangerous for you, the patient or any other person!

Therefore, we absolutely insist that before using it for the first time, all the persons who need to or want to use this device, must

- ***be authorised through training by briefing them about the medical background of defibrillation and the indications and contraindications!***
- ***read this operating manual and moreover, follow the safety instructions and the warnings given in it!***
- ***Doctors***

PRIMEDIC™ DefiMonitor XD *must be operated by trained and authorised persons only. Reading the operating manual is not a substitute for training.*

PRIMEDIC™ DefiMonitor XD *must* ***not*** *be used in areas where there is a danger of explosions.*

In case of improper use or use for a purpose other than for the intended purpose, the user (you), the patient or any other person is exposed to the

- ***risk of an electric shock through the high voltage generated by the device,***
- ***risk of getting affected by active implants***
- ***risk of burns if the electrodes are placed incorrectly***

Moreover, the device can be damaged or destroyed due to improper use!

Follow the rules and instructions listed in the appendix while using PRIMEDIC™ **DefiMonitor XD**!

During transportation of the DefiMonitor XD in a vehicle the Paddles have to be stored on the paddle rest, and the device must be placed on the wall mount rack.

For Europe, the following applies:

The device fulfils the provisions of the Medical Devices Act (MPG). In case of other countries of the European Union, the national regulations covering the operation of medical devices will apply.

The following regulations that apply in the Federal Republic of Germany additionally:

- The device fulfils the provisions of the Medical Devices Act (MPG – Medizinproduktegesetz) and is subject to the Medical Devices Operator Ordinance (MPBetreibV – Medizinprodukte-Betreiberverordnung).
- According to the Medical Devices Operator Ordinance (MPBetreibV), the device is subject to regular checks described in the appendix.
- According to the Medical Devices Operator Ordinance (MPBetreibV), a medical device book must be maintained for the device. Regular checks of the device must be recorded in it.

3.2 General Safety Instructions

Do not use the device in presence of flammable substances (e.g. petroleum ether etc.) or in an atmosphere enriched with oxygen or combustible gases / vapours!

3.3 Safety Instructions For You, The User

Use the device to treat a patient only if

- ***you are convinced of the functional safety and the proper condition of the device before using it!***
- ***the condition of the patient requires and / or permits using the device.***

Before using the device, check if the device is in the operating temperature range. This, for example, applies if the defibrillator is kept in an ambulance.

Do not use the device in case of any defect (e.g. if the defibrillation cable is damaged).

3.4 Safety Instructions for the Patient

Use the device to treat a patient only if you are convinced of the functional safety and the proper condition of the device before using it!

Before using the device, check if the device is in the operating temperature range. This, for example, applies if the defibrillator is kept in an ambulance in winter.

Do not use the device in case of any defect (e.g. if the defibrillation cable is damaged).

Use the device only with accessories, wearing parts and expendable articles whose suitability with regard to their safe use has been proved by a body authorised to test the ready usability of devices. All original PRIMEDIC™ accessories and wearing parts fulfil these conditions.

To avoid possible skin burns, use new and undamaged defibrillation electrodes falling within the expiry date for each patient!

Connect the adhesive electrodes only to PRIMEDIC™ **DefiMonitor XD***. The use of electrode systems with other devices can cause harmful leakage current to emit on to the patient.*

Do not operate the device in the immediate proximity of other sensitive equipment (e.g. measuring instruments that react sensitively to magnetic fields) or strong sources of interference that are likely to affect the functioning of PRIMEDIC™ DefiMonitor. Maintain adequate distance from other therapeutic and diagnostic energy sources (e.g. diathermy, high frequency surgery, magnetic spin tomography). These devices can affect PRIMEDIC™ DefiMonitor and interfere with its functioning.

During defibrillation, detach all other electronic devices used for medical purposes from the patient that do not have a defibrillation-proof user component.

Keep the defibrillation electrodes away from other electrodes and metallic parts that are in contact with the patient!

Do not use the device in Automatic mode for children under eight years or for children weighing less than 25 kg!

Place the electrodes exactly as described

Before placing the defibrillation electrodes, dry the patient's chest and carefully shave off any dense growth of hair.

Do not place the defibrillation electrodes directly over an implanted pacemaker. This will cause the device to interpret incorrectly and damage the pacemaker due to the defibrillation pulses.

Do not touch the patient during the ECG analysis and avoid any vibrations!

If the ECG analysis is conducted in a vehicle, then for a correct analysis, the vehicle must be stopped and the engine must be switched off.

Stop resuscitation while PRIMEDIC™ DefiMonitor is carrying out the ECG analysis.

Do not touch the patient during defibrillation! Avoid any contact between

- ***any parts of the patient's body (such as the bare skin of the head or the legs), as well as***
- ***conductive fluids (such as gels, blood or salt solution) and***
- ***metallic objects in the patient's surroundings (such as the bed frame or the stretcher) that represent an unintentional path for the defibrillation current!***

3.5 Safety Instructions For A Third Person

Before defibrillation, give a clear warning to any persons standing around to move away from the patient and not touch him!

3.6 Safety Instructions For The Device

- ***Any repairs, modifications, enhancements and installations of PRIMEDIC™ DefiMonitor XD must only be carried out by persons authorised and trained by METRAX!***
- ***No parts of PRIMEDIC™ DefiMonitor XD can be repaired by the user!***
- ***The device must be equipped and operated with original accessories from PRIMEDIC™ only!***
- ***Clean the device only when it has been switched off and the electrodes have been removed and only in the instructed manner!***

4 Device description

4.1 General Description

PRIMEDIC™ **DefiMonitor XD** is an automatic external defibrillator with integrated six-channel ECG. The ECG is carried out by PRIMEDIC™ SavePads, the Defibrillation paddles or by the three-pole patient cable. The DefiMonitor XD is organized modularly. Several models are available.

In **automatic mode** (Auto Mode) the ECG is analysed automatically by the algorithm used and detects the potentially fatal cardiac arrhythmias. In case a potentially fatal cardiac arrhythmia is detected, the defibrillator generates the electric shock required to revive the patient with an ECG rhythm treatable with a shock. In case the device does not detect a potentially fatal cardiac arrhythmia, the defibrillator does not generates the electric shock.

In **manual Mode the doctor ort he user has to decide himself,** if a defibrillation is required.

There are different models:

- **DefiMonitor XD1** basic model with monitor and 6-channel-ECG
- **DefiMonitor XD3** basic model with monitor, 6-channel-ECG and Pulseoximetry
- **DefiMonitor XD10** basic model with monitor, 6-channel-ECG and Pacer XD
- **DefiMonitor XD30** basic model with monitor, 6-channel-ECG, Pulseoximetry and Pacer XD
- **DefiMonitor XD100** basic model with monitor, 6-channel-ECG and Automatic Mode
- **DefiMonitor XD300** basic model with monitor, 6-channel-ECG, Pulseoximetry and Automatic Mode
- **DefiMonitor XD110** basic model with monitor, 6-channel-ECG, Pacer XD and Automatic Mode
- **DefiMonitor XD330** basic model with monitor, 6-channel-ECG, Pulseoximetry, Pacer XD and Automatic Mode

The PRIMEDIC™ **DefiMonitor** series was conceived and designed for quick and safe use in emergency situations. All the functional units and operating elements are subject to the following basic principles:

- Clear classification of functional units
- Limiting the functions to what is required
- Intuitive and logical operator guidance
- Clear, self-explanatory operating elements
- Ergonomic design

The ECG monitor has a high-resolution graphic display with a high image contrast even when the light is not good.

The defibrillator unit is optimised for safe and very quick operability.

The power supply for PRIMEDIC™ **DefiMonitor** takes place from rechargeable accumulators with nickel cadmium cells or through a power pack common for all models. The electronic charging is based on the latest technology and thus enables the maximum life of the accumulator used.

When not in use, the PRIMEDIC™ DefiMonitor XD can be kept in an optional wall unit that can fixed to a wall or in an ambulance. When required, it can be removed

quickly and easily with the help of an (optional) one-hand release. The electrical connections (power supply voltage or DC voltage) can be accommodated in the wall unit. The console also serves as power supply for charging the accumulators.

An extensive range of accessories is available.

The Wall Mount Rack and the accessories have been described in a separate operating manual.

4.2 Description of Device Details

Fig. 1 PRIMEDIC™ DefiMonitor – Front view

1 Handle
2 Paddles
3 Paddle cable, connectable
4 Keyboard
5 Monitor
6 Microphone
7 Status display

Fig. 2 PRIMEDIC™ DefiMonitor – Back view

1 Retainer opening for the fixation hooks
2 Type plate

Fig. 3 PRIMEDIC™ DefiMonitor – View from the bottom

1 Release button (to take out the power module)

2 Energy module

3 Cover SaveCard

Fig. 4 PRIMEDIC™ DefiMonitor – Side view

1 Speaker

2 Patient cable plug

3 SpO_2-Sensor plug (optional)

4 Paddle cable plug

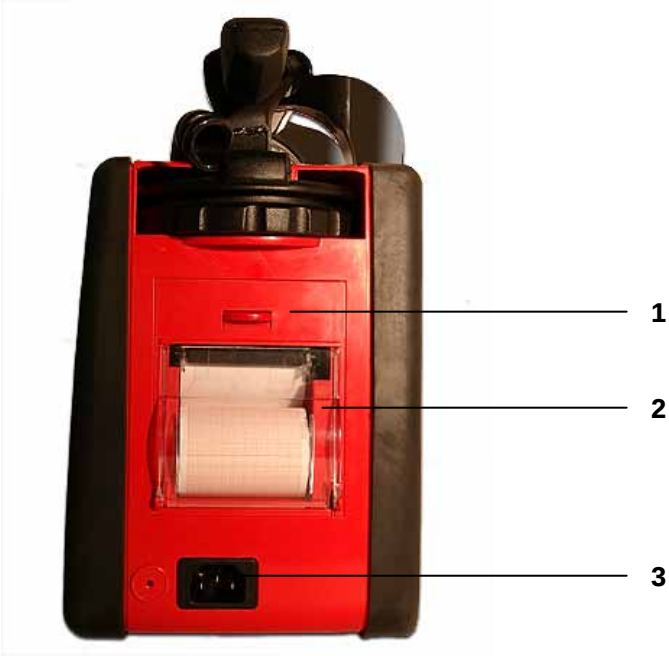


Fig. 5 PRIMEDIC™ DefiMonitor – Side view

1 Printer

2 Printer cover

3 AC Power cable plug

Fig. 6 PRIMEDIC™ DefiMonitor – Status-Display

Displayed Symbol	Meaning	Measure
■ ■ OK	– Self test passed – Battery / AkuPak capacity >30 %	– Device is ready for use
▭ ■ OK	– Discharged accumulator – Self test passed WARNUNG! VERLETZUNGS-GEFAHR Sign is also being displayed if no power supply was installed!	– Device can be used, the AkuPak might have to be charged or replaced – Please insert the AkuPak
■ 🔧	– Device might be defective – Device is defective	– Please carry out big self test by inserting AkuPak once again or switching on the device once again – Have the device repaired by your distributor

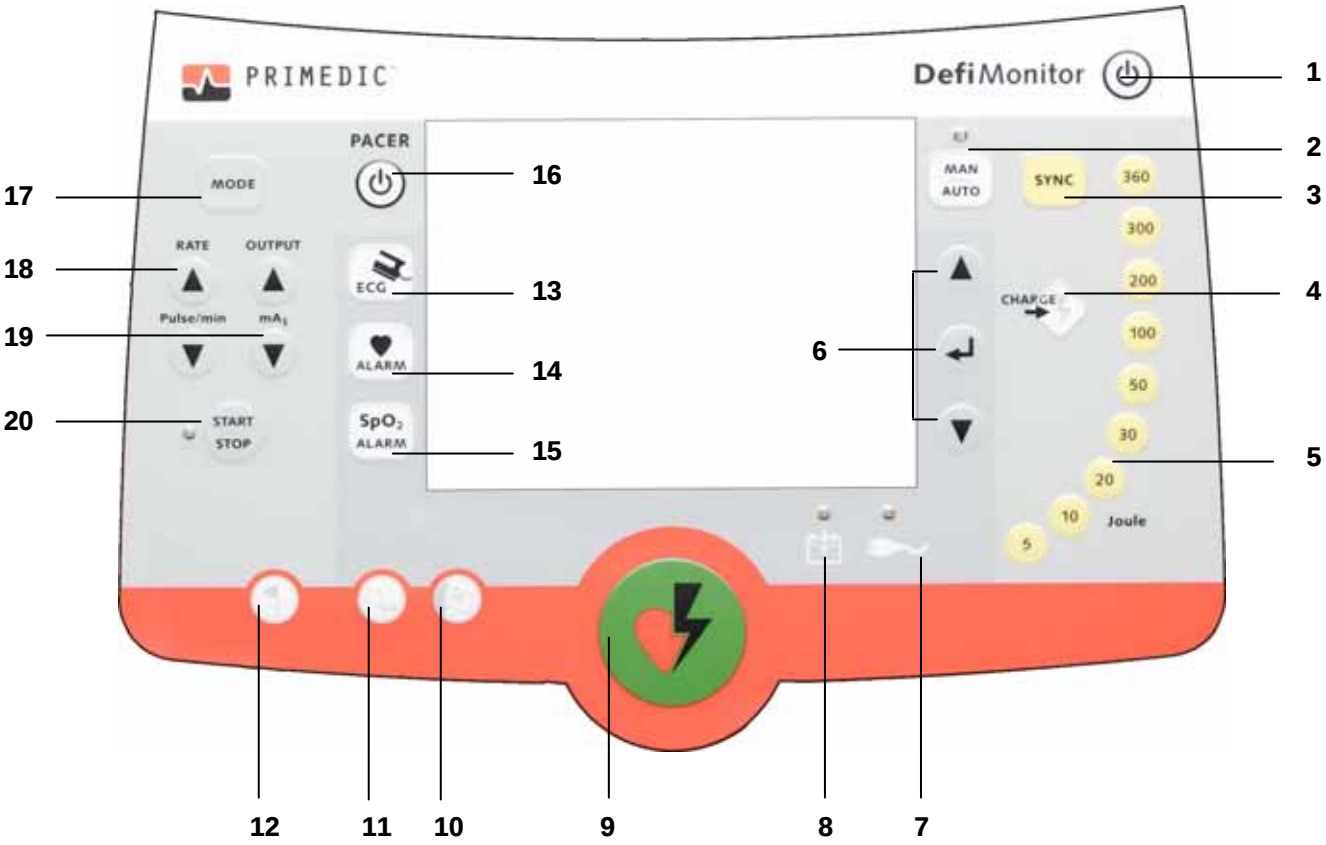


Fig. 7 Keyboard

1	*On- / Off button*	*11*	*Paper Feed button*
2	*Mode Switch Button AED/Manual*	*12*	*Event Marker*
3	*SYNC button*	*13*	*Paddle ECG button*
4	*Energy charging button for use of SavePads, can only be used in manual mode*	*14*	*Heart frequency alarm quit/mute button*
5	*Energy level selection in Joule (at 50 Ohm)*	*15*	*SpO2 alarm quit/mute button*
6	*Menue Buttons* *- Selection and Confirmation Button* *- Button to scroll up in the monitor menue and / or to increase parameters* *- Button to scroll down in the monitor menu and / or to reduce parameters*	*16*	*Pacer XD On- / Off button*
7	*LED Indication mains connection*	*17*	*Pacer Mode Switch button DEMAND/FIX/OVERDRIVE*
8	*LED indication" load accumulator"*	*18*	*Stimulation frequency +/-*
9	*Trigger button for defibrillation*	*19*	*Stimulation intensity +/-*
10	*Online Print*	*20*	*Start/Stop button*

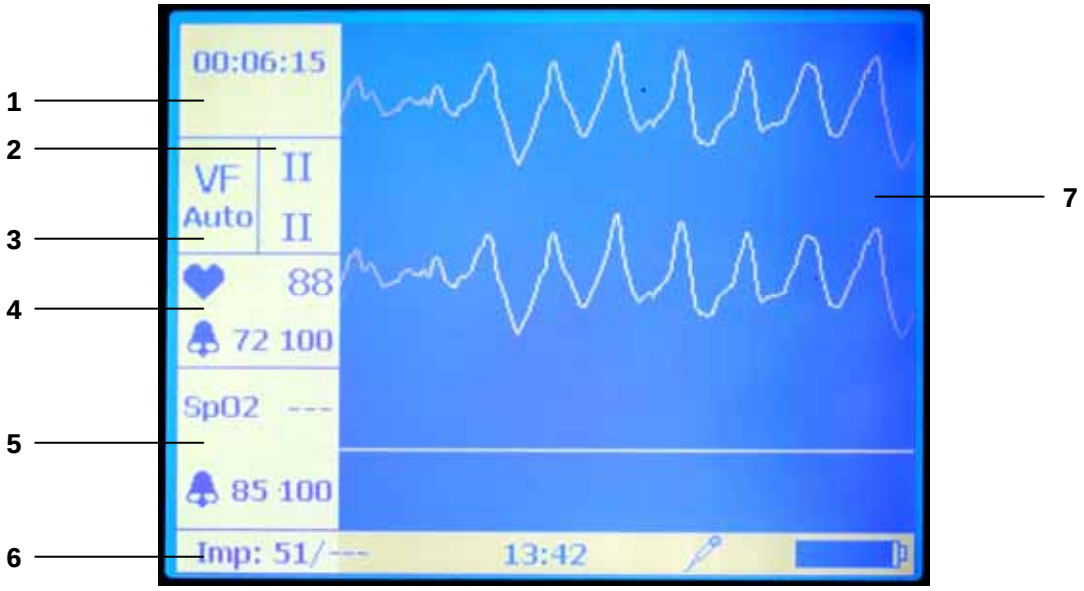


Fig. 8 Monitor display

1 Display of operating time or Pacer parameters

2 Mode AUTO/Manual

3 ECG channel display

4 Heart frequency and alarm settings display

5 Display SpO_2 and alarm settings display

6 Status line displaying patients impedance, time, microphone, battery status and reports

7 Display ECG and SpO_2 curve

4.3 Capacity Display

The charge level is shown in the display of DefiMonitor . The six possible display levels mean the following:

	100 % charged
	50% discharged
	Partly discharged and partly lost capacity of the AkuPak
	0% (Device will run until full depletion)

The AkuPak is monitored with the help of an electronic charge balance to ensure the best possible capacity display.

- In addition to this display, all DefiMonitor XD devices give a warning before the battery is completely exhausted.
- Should the AkuPak be damaged e.g. by memory effect, this will be indicated by the grey hatched part on the left side of the battery capacity symbol.

If the device is in use, every minute, there is a voice prompt in the selected language.

	Voice Prompt	Display in the Monitor
AkuPak	< Accumulator charge low, please charge >	Charge the accumulator

4.4 Data Management

The device automatically records all ECG data and all audio communication and surrounding sounds with a microphone on a detachable SaveCard .

The stored data can be displayed with the help of a PC or Laptop and the ECG Viewer software. The data is analysed exclusively for administrative or legal purposes and cannot be used for the diagnosis or treatment of the patient. The software has a job log in which further data about the patient can be entered.

If possible, data stored on the SaveCard should be archived on external media after each use. If the storage capacity of the SaveCard is exhausted, no further data will be stored. PRIMEDIC™ DefiMonitor can be used even if there is no space to store data and even without the SaveCard.

The operation of the software is described separately.

4.5 Accessory Description

4.5.1 Paddles

For paediatric defibrillation special electrodes with smaller surface have to be used. The paediatric paddles are integrated into the adult paddles. Therefore, kindly unscrew the big electrodes on both paddles anti-clockwise.

To screw the adult paddles onto the paediatric electrodes kindly turn clockwise.

Please clean the paediatric paddles after use, before re-attaching the adult paddles.

Please make sure the adult paddles are fixed tight, to ensure perfect contact.

4.5.2 SavePads AED

Fig. 9 PRIMEDIC™ SavePads AED, 2-pole

1 *Plug*
2 *Defibrillation-Electrodeswith protection cover*

4.5.3 EKG-Patient cable, 2-pole

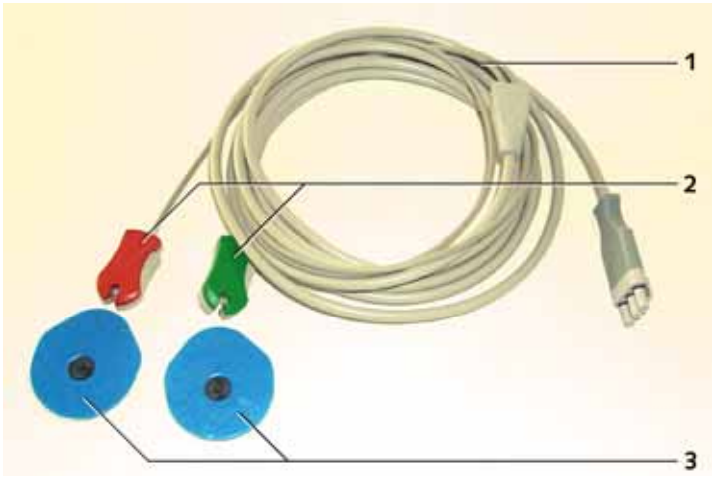


Fig. 11

1 *2-poe ECG-Electrode cable with connector*
2 *Electrode-Clipse (red, green)*
3 *ECG-Electrodes*

4.5.4 ECG-Patient cable, 3-pole

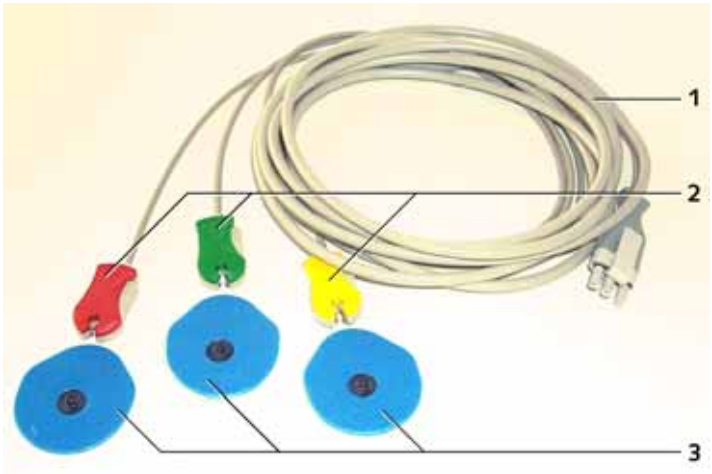


Fig. 12

1 *3-pole ECG-Electrode cable with connector*
2 *Electrode Clipse (red, green, yellow)*
3 *ECG-Electrodes*

4.5.5 SpO_2-Sensor (only for DefiMonitor XD3/30/330)

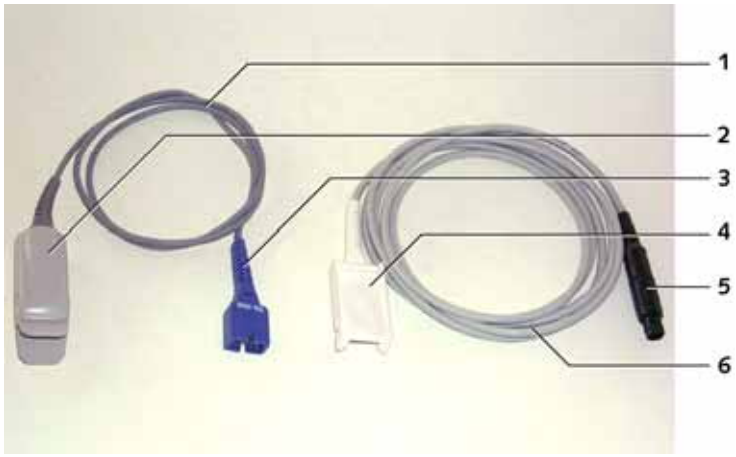


Fig. 13 SpO_2-Sensor and Adapter cable

1 *SpO_2-Sensor*
2 *Reusable SpO_2-Sensor*
3 *Connector (to connect Sensor cable and Adapter cable)*
4 *Socket (incl. locking)*
5 *Connector (to connect the Adapter Cable to Device)*
6 *Adapter cable*

5 Preparatory Measures Before (First) Operation

5.1 Unpacking

After delivery, check the packing and the device for any damage during transport.

In case you determine any damage to the device, contact your shipper, dealer or even the technical service of METRAX GmbH immediately. Give your serial number and describe the damage to the device.

Do not operate the device if any damage is detected. This can be physically dangerous.

Check the accompanying delivery note and make sure that all the equipment has been delivered.

Dispose off the packaging material in a non-polluting manner.

5.2 Inserting / Changing The SaveCard

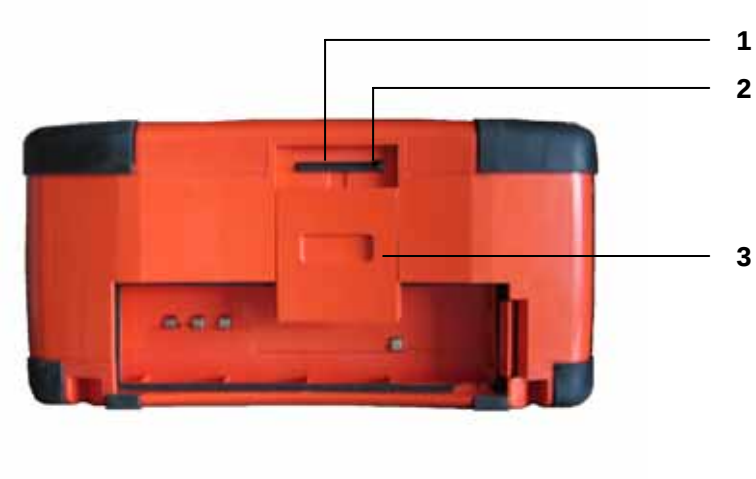


Fig. 14 PRIMEDIC™ DefiMonitor – SaveCard

1 SaveCard release button

2 SaveCard

3 Cover

5.2.1 Inserting the SaveCard

In order to insert the SaveCard, it is necessary to first disconnect the accumulator!

Before switching on the device for the first time, open the compartment by pushing the cover in the towards the power supply compartment. Afterwards, insert the SaveCard in the slot provided for it. Push the SaveCard into the slot as much as needed until button (1) will jut out.

Put in the power module now.

A file that is loaded automatically after switching on and / or after inserting the power module is saved on the SaveCard. This file contains the four languages relevant for your use. Then the DefiMonitor begins operation and runs the self-test. After the file is loaded by DefiMonitor, SaveCard does not delete it. Create a backup of the file afterwards. As the file uses about 4 MB of the storage space, we recommend that you delete the file with the help of a PC to create more space on the SaveCard.

After each use, the data stored on the SaveCard should be archived on external media as soon as possible. No further data can be stored if there is no space left on the SaveCard. PRIMEDIC™ DefiMonitor can be used even if there is no space to store data and even without the SaveCard.

5.2.2 Changing The SaveCard

To be able to remove / change the SaveCard, the power module must be removed first! Open the compartment by pushing the cover in the towards the power module compartment. Afterwards, push in button (1) completely – thereby a part of the SaveCard(2) is pushed out of the slot.

Remove the SaveCard from the device completely, transfer the data (if required) to a PC and insert this card or a new one with the connector side into the device first.

Press in the card lightly until the button (1) juts out from the opening.

Then put the power module back into the device.

5.3 Inserting / Changing the Power Supply Unit (Power Module)

PRIMEDIC™ DefiMonitor can be operated on two different power modules.

- *rechargeable AkuPak or*
- *via mains power supply.*

If you operate the DefiMonitor exclusively via the internal power pack, you must ensure that the AkuPak energy module shaft is inserted. Without it, the DefiMonitor cannot be operated.

Before using PRIMEDIC™ DefiMonitor for the first time, the power module must be inserted in the compartment provided for it.

Check the power supply after every use. Check whether the AkuPak should be charged. If this is not possible, another charged AkuPak should be available to ensure ready usability!

5.3.1 Inserting The Power Module

Fig. 15 PRIMEDIC™ DefiMonitor – Inserting the Power Module

Place the device on its rear side.

Push the (new) power module (2) in the direction of the arrow (1.) into the device until it fits at the back (3) as shown in the illustration.

Then press the power module in the front in the direction of the arrow (2.) into the compartment (1) until the release button (4) the tab of the power module are locked securely.

Push in the power module into the device completely until you hear the ‘click’ of the locking and the power module is locked evenly on the outer side of the device. If the power module falls out when the device is moved, it has not been locked correctly.

If the power module was placed correctly, the device switches on and carries out an automatic self test. Follow the acoustic / visual prompts of the device and switch the device off afterwards.

Watch the Status-display. If the display shows "OK", the device is ready to be used

Switch the device (if necessary) off by pressing the On/Off button.

Does the display not show "OK", resp. an error message appears on the Monitor, remove the cause or call your next service partner. The device switches off itself.

5.3.2 Removing The Power Module From The Device

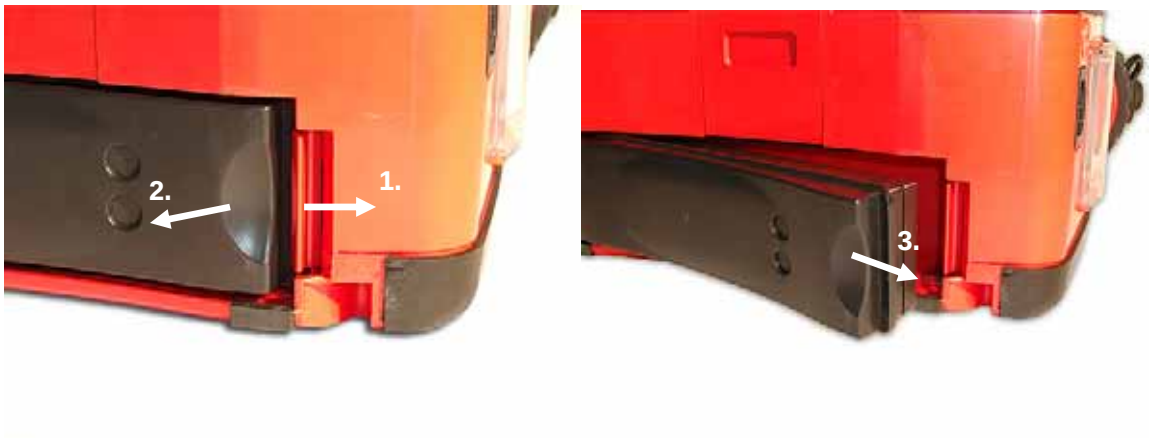


Fig. 16 PRIMEDIC™ DefiMonitor – Removing of the Power Module

Change the power module only when the device is switched off and the connector of the defibrillation electrodes is removed.

Place the device on its rear side and press the release button (1) in the direction of the arrow (1.) until the tab of the power module (2) is released and a part of the power module (3) springs out of the compartment (4).

Turn the power module slightly in the direction of the arrow (2.) and pull it out of the device in the direction of the arrow (3.).

5.4 Charging The AkuPak

The AkuPak can be charged in two ways:

- with the integrated AC Power module and / or
- in the wall mount rack (optional).

The integrated end-of-discharge detection protects the accumulator from total discharge. The end of charging is detected through the end-of-discharge voltage.

Charging the AkuPak at temperatures other than at the given operating temperatures can damage the accumulator.

A completely empty accumulator must be charged for at least 2 hours. Owing to the type of the accumulator, a very small charging time can lead to errors in interpreting charging by the device. The charging display can show a full accumulator by mistake. Safe operation of the device is also not guaranteed.

Shall the AkuPak not be charged or out of order, the DefiMonitor XD can also be used by means of the integrated mains power supply. The AkuPaks is automatically charged during the use of DefiMonitor XD. The charging time will be prolonged.

In case the device discovers an elevated temperature, it will interrupt the charging process until a normal temperature within a pre-defined value will be measured. This will avoid damaging the AkuPak during charging process.

5.4.1 Charging The AkuPak With The External Charging unit

Refer to the separate operating manual of the Wall Mount Rack for this.

5.5 Connecting The Powercord

Insert the powercord in the device socket and then insert the powercord into a socket near the patient. The powercord is around three meters long.

Make sure that the either the cover or the AkuPak are inserted into the power module compartment. This covering is mandatory to ensure peferct functioning of the device during mains power supply use.

5.6 Inserting the printer paper

In order to install the printer paper (paper roll) please push the release button above the paper compartment. The printer cover will open out to the front. Prepare the paper roll (remove tape, unroll paper approx. 5 cm). Insert paper roll into printer compartment with the squared side upwards. Close the cover.

The cover is constructed in a way that it will remove automatically without damage whenever force towards it will be exerted from outside. Place the cover back onto the initial position until the fixation will be audible.

5.7 Device Self Test

5.7.1 Self Test After Switch On Of DefiMonitor

The self test will either be activated when switching on the DefiMonitor or inserting the energy module into the device and passes immediately the device self test to check all important functions and signal settings.

If the energy module was changed and the DefiMonitor has located a failure the automatic self test (FULL) will take place. Follow the instructions of the DefiMonitor.

5.7.2 Automatic, Periodical self test

The device is carrying out automatic self tests in order to ensure full functionality. To do this, the DefiMonitor must either be connected to the power supplied or charged battery pack.

	Cycle	Test
SHORT	Daily	Software, keyboard, battery, ECG calibration, clock, internal voltage supply and HV part at 0 V
MEDIUM	First day of the month	Software, keyboard, battery, ECG calibration, clock, internal voltage supply and HV part at 300 V
LONG	On July 1st and January 1st of each year	Software, keyboard, battery, ECG calibration, clock, internal voltage supply and HV part at 1600 V

6 Operation Of The DefiMonitor XD

6.1 Switching On And Off

6.1.1 Switching PRIMEDIC™ DefiMonitor XD On

By pressing the On/Off button the device is switched on. Immediately after it has been switched, the device runs an internal self-test to check the important functions and signal equipment. After the auto-test has been passed, the device is ready for operation in AUTO mode.

All buttons are then enabled, except the shock button.

The activation of defibrillation is enabled by the DefiMonitor in auto mode only after the detection of ventricular fibrillation (VF) and/or pulse-free ventricular tachycardia (VT).

A signal tone confirms that the device is ready for operation. Always check the functioning of the speaker.

6.1.2 Switching PRIMEDIC™ DefiMonitor XD Off

The PRIMEDIC™ DefiMonitor can be switched off in many ways:

- By pressing the On/Standby button for about two seconds. At the same time, there are three warning tones. This time is selected so that the device is not switched off by mistake.
- If the device does not detect a signal for ten minutes or if no button is pressed, it is switched off automatically.

If the device detects any defect, it switches off automatically to prevent any possible injuries.

6.2 Choosing Operating Mode and Changing the Configuration

The device is configured by the factory.

Switch the device on as described before.

Certain parameters in the Setup Menu (displayed on the monitor) can be changed. This configuration is stored and retained until a new change is carried out, whether the device is off or the power supply is changed.

To activate the Setup Menu, press the Selection and Confirmation button ↵during operation.

Use

- the ▲ button (upwards) or
- the ▼ button (downwards)

to navigate in the menu and to increase or to reduce a selected parameter and the ↵ button (to select a parameter and confirm the changed value).

Setup

Following parameters can be changed on the pages of the Setup Menu:

page 1	
printing-speed:	[25 mm/s / 50 mm/s]
filter:	(on / off)
printing-channel:	1 channel / 2-channel
auto-print:	(on / off)
memo-print:	action
MMI-test	action
page 2	
language	German / English / Polish
date:	in format dd/mm/yyyy
time:	00:00 in 24 hours format
volume:	(25% / 50% / 75% / 100%)
contrast:	40 to 120
microphone:	(on / off)
BLS advice	(on / off)
display	(0 degree / 180 degree)
page 3	
voice-output	(on / off)
lead	display-channel 1 displaychannel 2
alarm ecg	low limit high limit
alarm ecg	(on / off)
alarm SpO2	low limit high limit
alarm SpO2	(on / off)
sytole-tone	(on / off)
page 4	
ARM SW	x.xx(version-no.) xxxx (control-sum 4-digits) date (e.g. Jul 11 2005)
DSP SW	x.xx(version-no.) xxxx (control-sum 4-digits) date (e.g. Jul 11 2005)
MSP SW	x.xx(version-no.) xxxx (control-sum 4-digits) date (e.g. Jul 11 2005)
ULF:	control-sum
serial-no.	x
page 5	
BQ SW version	x.x
BQ serial-no.	x
ext. MSP SW	x.xx(version-no.) xxxx (control-sum 4-digits)
ext. MSP SW	x.xx(version-no.) xxxx (control-sum 4-digits)

Changing the Configuration – Example

On entering the Setup Menu, the first item in the menu is selected.

For example, if you want to update the time, move the selection downwards by pressing the ▼ button once or more until the item **Time** is selected.

Confirm the selected menu item **Time** by pressing the ↵ button. The selection jumps to hours.

Change the hour by pressing the ▲ or ▼ button.

Confirm the correct value with the ↵button. The selection then jumps to minutes and then to seconds.

Change these values in the manner described above. After the final confirmation with the ↵button, the selection once again jumps to the menu item **Time**.

Now carry out any other changes (if required) in the same manner.

To exit the Setup Menu, move the selection with the ▲ or ▼ button to the menu item **END** and confirm this with the ↵button.

PRIMEDIC™ DefiMonitor is then ready for operation again.

6.2.1 Choosing The Operation Mode

The DefiMonitor XD100 / XD110 / XD300 / XD330 offers two different operating modes:

- *The AUTO-Mode and*

- *The MANUAL Mode*

6.2.2 Auto Mode

After switching on and successfully passed self test the device always operates in **Auto Mode**.

This operation mode carries out an automatic ECG-Rhythm-Analysis.

If the device clearly detects VF or VT, it recommends a defibrillation and prepares for it internally and automatically and recommends to deliver a defibrillation to the patient. If the device does not detect a rhythm requiring defibrillation, it recommends cardiopulmonary resuscitation.

6.2.3 Manual Mode

By pressing the button MAN/AUTO again the DefiMonitor will be switched to Manual mode. The manual mode is not activated.

Switch to operation mode AUTO

- *By switching the device off and on again or*
- By pressing the button Man/AUTO.

6.3 Alarms

The alarms (heart rate and SpO_2) are inactive after switching on which is indicated on the monitor.

The setting range for the lower alarm limit is in the range of 30 -180, with the upper alarm limit of 60-300. This is displayed in the monitor. The alarms can be activated in

the Setup menue. After acknowledging ALARM press the alarm button that the acoustical alarm is suppressed for about 1 minute.

Display in the monitor (e.g. ALARM 30 / 90, SpO_2 90 / 100) means that if the heart frequency is exceeded by 90 beats/minute or if it is less than 30 beats / minute, a rhythmical alarm sounds. The alarm bell symbol flashes If the alarm sounds you can acknowledge this (shut off) by briefly pressing the alarm key. The alarm key is shut off for approx. 1 minute but the alarm limits remain. When the mute setting is activated, the alarm bell symbol appears crossed-out.

The heart alarm is automatically set to **OFF** after defibrillation.

6.4 Event

A mark is placed by pressing the event key in the EKG which saves the EKG 5 seconds before and 5 seconds after the event. This event can then be printed out later with the event memory and/or viewed in the saved patient vile on the PC using the EKG viewer.

6.5 Operating The Printer

The printer can only be used in Manual mode.

6.5.1 Log of the ECG Signal

The PRIMEDIC™ **Defi**Monitor XD has a printer with high resolution. An EKG pressure with 3 to 6 channels simultaneously is possible. 25 and 50 mm/s print speed is available.

The online print starts to log the EKS curve during monitoring by pressing the Printer On/Off key.

Pressing the printer ON/OFF key stops the log printout. The EKG printout occurs with the parameters which are selected in the setup menu. The following settings are available:

1-channel print	prints the EKG channel shown in the monitor. If the SpO_2 measurement is active, the Spo_2 pulse curve is also shown.
3-channel print	prints the channels I,II, III or aVR, aVL, aVF simultaneously, depending on which derivation is shown in the monitor.
6-channel pressure	prints the maximum possible derivations I, II. III, aVR, aVL, aVF in real time, depending on the connected electrodes, in 3 blocks.
25 mm/s – print speed	The printout is at 25 mm/s.
50 mm/s – print speed	The printout is at 50 mm/s.

All relevant parameters are printed out in a data paragraph:

Date, time
Energy (Joule)
Synchronised / asynchronised mode
Derivation
Heart frequency
Signal reinforcement
Lines for later notes (e.g. patient note etc.)
SpO_2-value (only model XD 3, 30, 300 and 330)
Speed

In the device versions with SpO_2 measurement, it is possible to show the SpO_2 pulse curve in the log printout.

The printout is at a 5 second delay to the monitor display, i.e. events before the activation of the printout can be shown. If the printput is stopped, the printout ends 5 seconds in the past.

To separate the EKG log strip, use the integrated tear-off edge on the printer cover. Detathc the papert strip laterally in an upward motion.

Systematic and brief printing saves energy and paper and extends the operating time in which the device can work independently of the power supply. This particularly applies to printing with 50 mm feed speed.

6.5.2 Automatic Printout after Each Shock (Autoprint)

The PRIMEDIC™ Defimonitor offers the ability to log the event automatically according to defibrillation / cardio version. Here the results are documented 5 seconds before and 5 seconds after the shock.

The Autoprint function can be switched on and off in the setup menu. The function is switched off in delivery state.

If the Autoprint function was switched on in the setup menu, this stays active, even after shutting off the defibrillator or changing the battery. To deactivate this function, you must change the device configuration in the setup menu.

6.5.3 Printout of the Result Memory

The PRIMEDIC™ DefiMonitor saves the last 30 defibrillations / cardio versions / events automatically in an event memory. Here the EKG is saved (5 seconds before and 5 seconds after the shock), the pulse curve (only at XD 3, 30, 300 or 330 if SPO_2 is active, as well as all relevant parameters.

A newly added result “pushes“ the oldest result from the memory.

The memory content, beginning with the last recorded event, is print out from the setup menu.

Go to the setup menu and select the menu item “Memo Print” with the cursor keys. Confirm the point “activate“. The memo-print starts. To stop the printout confirm with the printer on/off key. The printout is at 25 mm/s.

The data in the result memory also remain after the printout. They can be printed out any number of times.

7 Positioning Of The Electrodes

7.1 Undressing The Patient

If, after the preliminary examination, the patient needs to be defibrillated, undress the upper part of his body to be able to place the electrodes.

7.1.1 Determining The Position Of Electrodes

For SavePads and Paddles

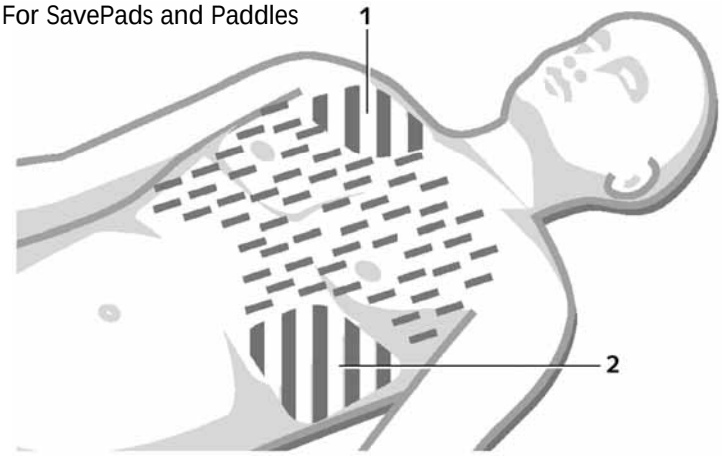


Fig. 17 Position of Electrodes on the Patient

The electrodes are positioned

- in the region of the right breast, below the collarbone (1) and
- in the region of the left breast above the apex of the heart on the auxiliary line (2).

A false positioning of the electrodes can force misinterpretation.

7.1.2 Positioning of Pacer - / Defibrillator electrodes for Pacing

Two different electrode positions have been established for heart stimulation:

- anterior - anterior position
- anterior - posterior position

The position and the polarity of the electrodes have a great influence on the necessary stimulation intensity and on the comfort of the patient during stimulation.

The preferred position is the anterior- posterior position.

Electrode connector	Color	Position
Anterior	Blue (-)	left frontal chest side, between chest bone and left nipple (approximately V_2/V_3-Position)
Posterior	White (+)	left dorsal chest side, between tip of shoulder blade and spinal column

The anterior posterior position has the advantage that the stimulation intensity will be lower and therefore the cheat muscles will be less stimulated. This has a positive influence on the physical comfort of the patient.

If the anterior-posterior position is contraindicated (e.g. if the onset of ventricular fibrillation is likely), alternatively the anterior - anterior position might be used.

The position corresponds to the paddle position during defibrillation.

		Position
Anterior	Blue (-)	respective Apex position, left frontal chest area, over apex on the auxiliary line
Anterior	White (+)	respective Sternum position, right frontal cheat area beyond collarbone

To prevent the danger of electrocution it is important to pay attention to the following order when attaching the adhesive electrodes. First connect the patient cable with the snap-in connector with the attached electrodes at the patient. Then connect electrode cable with the DefiMonitor.

If a defibrillation is indicated during pacing, defibrillation might be done by with the Pacer electrodes. Note the electrode position when doing a defibrillation.

Adults may only be paced with respective electrodes for adults, children only with the respective paediatric electrodes.

Use only original PRIMEDIC™ Pacer-/Defibrillation electrodes.

7.2 Opening SavePads

Open the packing of the electrodes by tearing open the protective covering.

7.3 Removing the Chest Hair

If the patient has hair on the electrodes' positions, then it must be shaved off.

Shave off the hair at the electrodes' positions with the given shaver.

7.4 Connecting The Electrodes

Remove the electrodes from the SavePads pack.

Insert the connector of the electrode cable in the socket of theswitched on DefiMonitor.

Pay attention that the lock engages.

In order to remove the defibrillation electrode plug you must push firmly on the upper part of the catch and simultaneously pull out the plug.

7.4.1 Pulling Off The Protective Sheet On The Electrodes And Placing the Electrodes

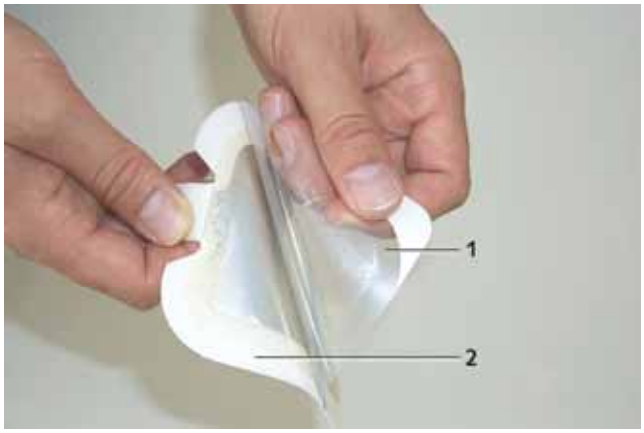


Fig. 19 Pulling off the Protective Sheet on the Electrodes

The PRIMEDIC™ DefiMonitor instructs you to place the defibrillation electrodes on the patient through voice prompts.

Proceed in the following manner:

First pull off the protective sheet (1) from one electrode (2) and then place the electrode directly on the position determined earlier.

Then pull off the protective sheet of the second electrode and place it on its position.

Press the electrodes on the patient so that there is no air cushion under the electrodes! This display "Check electrodes" must go off.

Do not the touch the ground, objects, clothing or other parts of the body with the electrodes (after the protective sheet has been removed). This might remove the conductible gel coating on the electrodes.

An insufficient coating of gel could lead to burns on the skin under the electrodes during defibrillation!

Please check that

– the indicator in the display is off.

See the short operator guidance on the SavePads package.

Output in the display is suppressed in the device versions with SpO2.

7.5 Check Electrodes

If the device detects an error, it can be due to several reasons:

- **There is a contact and / or a conductive gel connection between the defibrillation electrodes.**
- **The hair on the patient's body has not been shaved.**
- **Trapped air between the skin and the defibrillation electrodes causes a bad contact.**
- **Electrodes have dried out.**

Eliminate the cause of the problem!

8 Auto Mode

The process of resuscitation by this device has been devised in accordance with the American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines.

After the device is switched on, after the auto-test is completed and after the operating mode is selected, the device is ready for use.

8.1 Voice Prompts / Preliminary Examination Of The Patient

The voice prompts instruct you to examine the patient.

After the device has completed the self-test successfully, the following instructions are given:

< Check responsiveness >

< Call emergency >

< Check circulation >

< Open airway, check mouth cavity and respiratory tracks >

< Carefully overstretch head >

< Check breathing >

< If no breathing, give twice respiration >

< put the plug in >

< Place electrodes >

Carry out the instructed tasks before placing the electrodes on the patient!

The line-up of tasks is automatically interrupted if the electrodes are applied to the patient.

8.2 Carrying Out The ECG Analysis in Auto Mode

The device starts the analysis automatically if the defibrillation electrodes are placed correctly. The automatic analysis functions exclusively via the defibrillation electrodes.

Now the patient must be kept still and not be touched.

The device prompts

< Do not touch the patient, rhythm analysis >

The algorithm of the device program now checks the ECG for a shockable rhythm. This process takes about twelve seconds. The device recommends a defibrillation if it detects VF and VT.

Observe the patient constantly during the entire process of resuscitation.

The patient might regain consciousness at any time and must not be defibrillated.

Stop the defibrillation immediately!

The rhythm detection system analyses the ECG constantly and continues the analysis even after a rhythm requiring defibrillation is detected.

8.3 Defibrillation Required

If the device clearly detects VF or VT, it recommends a defibrillation and prepares for it internally and automatically.

The device prompts

< Shock recommended, do not touch the patient >

If the capacitor is charged internally, energy required for a defibrillation pulse for 15 seconds is available and is indicated by a continuous tone and the 'green' trigger button. The model with the monitor also shows the time left. If defibrillation is not carried out within this time, a safety discharge takes place internally and the ECG analysis is carried out once again.

Before activating the release button, remove all devices connected to the patient that are not protected against defibrillation!

Before and during the discharge of energy, all persons participating in the resuscitation measures must step back and all contact with the patient or conductible objects (e.g. a stretcher) must be avoided!

Hold down the key until the discharge has occurred. Avoid contact with the device sockets during defibrillation.

After defibrillation, the analysis starts again. If the algorithm again detects VF or VT, it enables the defibrillator again. This process is repeated three times in all, after which there is a one-minute interval for the cardiopulmonary resuscitation (CPR).

The time required to prepare for defibrillation depends on the available capacity of the battery / accumulator. The charging time can be a little more in case of a partly discharged power module.

If there is an error during charging, there is a continuous warning tone and the existing charge in the capacitor is discharged within the device.

- ***In case of the message "Charge accumulator", there is still a five-minute energy discharge with maximum energy. The power module should be replaced if this message appears.***
- *If an ECG is not recorded or no button is pressed for15 minutes after the device has been switched on, it switches off automatically. There is a continuous warning tone for about 30 seconds before it switches off. Any random operation stops the automatic switch-off.*
- *When the electrodes are not connected, the model with the monitor shows a straight line with the instruction 'Check electrodes' in its initial state. As soon as there is a lead through the electrodes, the ECG signal is displayed on the monitor.*

8.4 Defibrillation Not Required

If the device does not detect a rhythm requiring defibrillation, it recommends cardio-pulmonary resuscitation.

< One minute cardiopulmonary resuscitation >

After the CPR sequence has finished the DefiMonitor will start the ECG analysis automatically again.

8.5 Keeping The Defibrillator Ready For Use

Clean the device after resuscitation, replace the SavePads and check and / or change the power supply unit if required, so that PRIMEDIC™ DefiMonitor can be used as fast as possible on the next use. Charge the AkuPak for sufficient power on the next use.

Contact the nearest service station in case of any faults or irregularities as soon as possible.

9 Manual Mode

*After switching on and successfully passed self test the device always operates in **Auto Mode**. If you own a strictly manual device, switching is not necessary.*

To activate the Manual Mode, press the setup button MAN/AUTO once. The monitor will show MAN. The operating mode "Manual" is now activated.

9.1 Carrying out of the Defibrillation

In opposition to the **Auto Mode** (in which the device's Algorithm analyzes the ECG and recommends a defibrillation), the doctor or the user has to examine the patient's ECG himself if the patient has a shockable rhythm. 2 shock methods are available to provide the defibrillation pulse.

1. Via the SavePads

2. Via the paddles

The decisive factor fort he shock method is where you start the energy charge. If you charge the energy by pressing the paddle key, the energy can be transmitted only via paddles. Press the charge key on the film keyboard; the energy is then only transmitted via the save pads.

Decide, if there is a defibrillation necessary and when it must be released to the patient.

9.1.1 Choose Energy

Choose the most suitable energy level by using energy level buttons for the defibrillation first. The energy levels are 5, 10, 20, 30, 50, 100, 200, 300, 360 Joules are shown on the right side of the monitor. The selected energy is displayed in the monitor as a confirmation for the energy setting.

The energy level for the Defibrillation / Cardioversion is depending on the patient's size, weight, shape and impedance. Please note also the displayed impedance on the status bar as a further aid to determine the energy level.

9.1.2 Charge Energy

Press the energy charging key depending on the shock method (see above)

The selected energy is loaded by pressing the energy charge key and is ready for operation to provide a defibrillation after a short time. Ensure that the energy level you have selected is shown in the display.

If the energy is transmitted via the SavePads and if charging is completed, the green activation key lights up and a warning signal is also given.

If the energy is transmitted via the paddles, a warning sound is given.

If a wrong energy level is selected and if the energy for defibrillation was already charged, discharge by pressing on the charge key on the film keyboard again. The charged energy will internally be safety discharged. Choose the new energy level and press the manual charge button again. A charged energy can not be corrected.

If the capacitor is charged internally, energy required for a defibrillation pulse for 15 seconds is available and is indicated by a continuous tone and the 'green' trigger button. The time left is shown on the monitor. If defibrillation is not carried out within this time, a safety discharge takes place internally. By pressing the manual charge button within the 15 seconds again the energy can also be safety discharged internally.

Before delivering the defibrillation remove all devices which are applied to the patient and are not protected against defibrillation impulses.

Before and during the discharge of energy, all persons participating in the resuscitation measures must step back and all contact with the patient or conductible objects (e.g. a stretcher) must be avoided!

The time required to prepare for defibrillation depends on the available capacity of the battery / accumulator. The charging time can be a little more in case of a partly discharged power module.

If there is an error during charging, there is a continuous warning tone and the charged energy will be safety discharged internally.

9.1.3 Discharge Energy

Confirm the activation key or both paddle keys to confirm defibrillation, which occurs after the button was pressed. Hold down the key until the discharge has occurred. Avoid contact with the device sockets during defibrillation.

The contact surfaces of the paddle must have sufficient electrode gel in order to prevent burns to the skin.

When the defibrillation is carried out, you must check the EKG again for rhythms which are suitable for a shock and if necessary activate (a) further defibrillation(s) (or more extensive resuscitation measures).

– ***In case of the message "Charge accumulator", there is still five energy discharges with maximum energy. The power module should be replaced if this message appears.***

9.2 SYNC and ASYNC Mode

If the emergency situation requires a synchronised operating mode of the defibrillator (cardio version), this must be a conscious choice by selecting the SYNC key. To go to SYNC mode, the defibrillator must first be switched to manual mode. You can then activate SYNC mode by pressing the SYNC key. The synchronised operating mode is shown on the EKG monitor with the notice "SYNC.

In order to guarantee more precise synchronization, synchronization via the defibrillation adhesive electrodes is recommended. As a result, the movement artefacts can be essentially avoided. It is also possible to synchronise with the paddle. To do this, the EKG must be derived via the paddle and you must ensure that the synchronisation is not distorted by the movement artifacts.

After synchronised energy transmission (cardio version) the Defibrillation unit switches back to asynchronous mode.

In the synchronised mode, the EKG marks are shown on the monitor screen. For a secure synchronised mode, the cardio version markers in each QRS complex must appear directly with an R-peak. The prerequisite for this is a clean, artefact-free EKG signal.

The Synchronisation can only be used for lead II.

The delay time is less than 60 ms between detection of a QRS complex (synchronised pulse) and energy transmission.

Before releasing the cardioversion check on the monitor whether the cardioversion markers are clearly related to the R-peaks and do not react e. g. to pacemaker pulses or artefacts.

The AUTO-SYNC is only available in the Manual Mode and is only carried out on lead II.

In case of synchronous operation the release button has to be pressed down until the moment for the cardioversion is reached. During this time an intermittent signal will be on. No cardioversion will be released, if during discharging the release buttons are let go off. The energy is discharged internally if no synchronisation takes place within 3 seconds while keeping the release button pressed down.

If the activation button is only pressed briefly and if the defibrillation is not triggered by synchronised markers, the energy remains in the capacitor.

The energies required for synchronized cardioversion are in most cases lower than for defibrillation (unsynchronized cardioversion) as it is not necessary to depolarize all heart muscles.

The energy depends roughly on the patient's body height and weight. The indications, however, determine the energy, i. e. the following empirical values are applicable:

Ventricular tachycardia with unstable pulse:	50 joule, further cardioversions to be increased by approx. 50 joule each (100 j, 200 j, ...)
Supraventricular tachycardia:	50 - 100 Joule
Atrial flutter:	50 Joule
Atrial fibrillation:	100 Joule

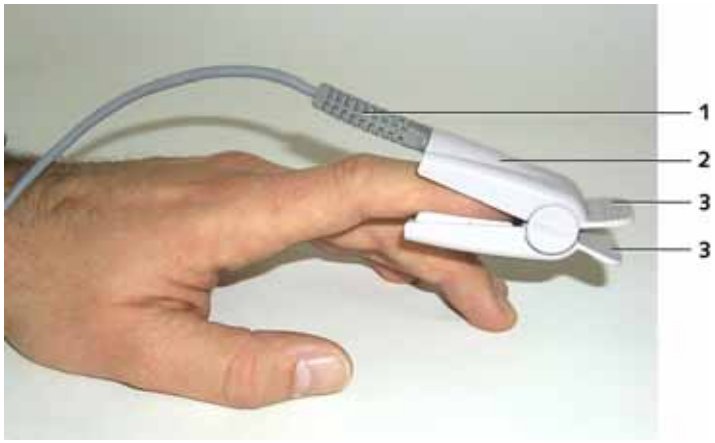
The above mentioned values are only recommendations.

9.3 Keeping The Defibrillator Ready For Use

Clean the device after resuscitation, replace the SavePads and check and / or change the power supply unit if required, so that PRIMEDIC™ DefiMonitor can be used as fast as possible on the next use. Charge the AkuPak for sufficient power on the next use.

Contact the nearest service station in case of any faults or irregularities as soon as possible.

10 Apply the SpO_2-Sensor



1 cable protection
2 SpO_2 – Sensor
3 pad

Fig. 24 Apply the SpO_2-Sensor

Press the two pads (3) together and push the opened sensor on any finger, so that the cable / socket side of the sensor is located on the finger nail side.

Reusable sensors may remain at one measuring point for 4 h maximally, provided that state of the skin, the correct and secure positioning of the sensor at the measuring point are controlled regularly. As the tolerance towards sensors at the measuring point depends upon the individual condition of the skin, it may be necessary to change the points of measure with some patients.

10.1 Connect the SpO_2-Sensor

- Connect the SpO_2-Sensor plug (1) into the socket of the device, the arrow (3) at the plug and the arrow (4) at the socket must match together. Make sure that the plug has been connected completely before you use it.

To disconnect the connector, lift the sleeve with arrow first up and then pull the connector out from the socket.

11 Operation Of The Pacer

11.1 Switching On and Off

While using the PRIMEDIC™ **Pacer XD** the following operating order must be considered:

- Switch PRIMEDIC™ DefiMonitor XD on.
- Apply adhesive electrodes to patient.
- Connect adhesive electrodes with snap-in connector with the SavePads Plus cable. This is done by first opening the snap-in connector with the lid. The metal flap connector of the electrode is inserted into the slit of the snap-in connector. Close the lid to fixate the connection. Pay attention to the color marking for the polarity of the respective connector at the electrode position.
- Connect SavePads Plus cable to the socket at the DefiMonitor.
- Attach ECG electrodes to the patient and connect ECG patient cable with socket of PRIMEDIC™ DefiMonitor.
- Switch on PRIMEDIC™ Pacer XD.

The PRIMEDIC™ Pacer XD is switched on by a short press of the Pacer On- / Off-key. The Pacer XD does not yet generate stimulation impulses. First the parameters

Operating mode

Stimulation Frequency

Stimulation Intensity

need to be set and the Pacer must be started.

The PRIMEDIC™ Pacer XD is switched off by pressing the Pacer On- / Off-key. Simultaneously 3 acoustic warning signals are given.

If the PRIMEDIC™ Pacer XD is activated without the Pacer- / Defibrillation cable connected to the socket of the Pacer XD, an acoustic warning is emitted and the message “Pacer Electrodes Open” appears on the monitor.

If a warning sounds after activating the pacer for each pacemaker impulse, the device has detected a deviation of ± 15 % from the set intensity. A possible cause of this can be patient resistance that is too great. If a deviation of ± 30 % is detected, the device interrupts the pacer process automatically.

The Pacer XD is powered by the battery of the PRIMEDIC™ Defi-Monitor. Therefore, monitor the battery capacity gauge in the monitor during pacing. If the message “Charge Accu” appears, the battery has to be recharged or exchanged to continue the stimulation. If the Pacer is used with low battery harm to the patient by device failures is possible.

If the activated PRIMEDIC™ pacer is operated for longer than 3 minutes, it switches off automatically.

11.2 Operation Pacer mode setting

Three different operation modes for the Pacer are available:

- DEMAND (Default)
- FIX
- OVERDRIVE

Operation Mode	Features
DEMAND (Default)	The stimulation occurs only on demand, which means only if the inherent heart frequency decreases under the DEMAND-frequency value.
FIX	Fixed frequency stimulation, which means independently from the inherent heart rate a fixed heart rate is forced.
OVERDRIVE	Over stimulation of the heart with a high frequency (max. 250 ^{1}/min) to terminate e.g. ventricular tachycardia.

After switching the device on, the operation mode DEMAND is automatically activated. The operation mode is displayed in the monitor in a text window. To switch to another operation mode press the operation mode key once or several times until the desired operation mode is displayed.

While setting the operation mode, stimulation impulses are not yet generated.

During pacing, the operation modes can not be switched. Before switching e.g. between FIX and DEMAND mode, the Pacer has to be stopped.

If pacing is reactivated without a change of the operation mode the previously set stimulation parameters are applied. if the operation mode is switched, or the Pacer is switched off and on again, the default stimulation parameters are reactivated.

11.3 Stimulation frequency setting

Depending on the operation mode of the Pacer different stimulation frequencies (number of pacing impulses per minute) can be set:

FIX, DEMAND 30 ... 180 ^{1}/min

OVERDRIVE 30 ... 250 ^{1}/min

When activating the respective mode the following frequency values are pre-set:

FIX, DEMAND 70 ^{1}/min

OVERDRIVE 250 ^{1}/min

If a different stimulation frequency is indicated, the frequency can be changed by the Pacer-Frequency + key or the Pacer-Frequency - key. The alteration occurs with each key press in steps of 5 ^{1}/min upwards or downwards. The stimulation frequency can also be altered during pacing.

If the keys Pacer-Frequency + or - are pressed continuously, the frequency is stepped each half second. If the key is released, the frequency remains at the last adjusted value.

The stimulation frequency should only be adjusted if this is absolutely necessary. Alterations need to be done under strict ECG monitoring, since the patient, under certain circumstances, will react differently on the new stimulation parameters.

11.4 Stimulation intensity setting

After switching the PRIMEDIC™ Pacer XD on a current intensity of 10 mA is pre-set independent of the chosen operation mode or frequency.

The stimulation intensity can be adjusted by the keys Pacer-Intensity + and Pacer-Intensity - . The alteration occurs with each key press in steps of 5 [1]/min upwards or downwards. The stimulation frequency can also be altered during pacing.

If the keys Pacer-Intensity + or - are pressed continuously, the frequency is stepped each half second. If the key is released, the frequency remains at the last adjusted value.

If one of the pacer intensity keys + or – is depressed for an extended period of time, the current level is changed by an increment of 5 every half second. The value last set remains if the key is released.

The magnitude of the stimulation intensity is dependent of the physical condition of the patient. The current intensity should be adjusted in a way that its effect can be seen in the ECG monitored.

The magnitude of the intensity is a compromise between a good and effective stimulation of the heart and an eventually necessary sedation of the patient. If the stimulation effects are clearly visible in the ECG, by carefully degreasing the intensity the optimal intensity might be adjusted.

Pacing goes along with the contraction of skeletal muscles. This is not an indication for effective heart stimulation. Always monitor the patients ECG to evaluate a sufficient pacing intensity.

11.5 Start And Stop Pacing

The operation mode of the PRIMEDIC™ Pacer XD needs to be set before pacing is started. During pacing a change of the operation mode is not possible. The set operation mode is displayed in the monitor.

By pressing the key Stimulation Start/Stop, stimulation starts with the pre-set parameters. This is acknowledged, with an acoustic signal. The operation mode indication text in the monitor flashes. With each pacing impulse, the Pacing-LED flashes.

To stop the stimulation press the key Stimulation Start/Stop for a short time, which is acknowledged by an acoustical signal. The indication text in the monitor stops flashing.

Limited stimulation duration in the OVERDRIVE-Mode:

To prevent a harmful excessive stimulation in the OVERDRIVE-Mode, the stimulation period without any user adjustments is limited to 15 seconds.

After starting the stimulation with the key Stimulation Start/Stop the stimulation is started with the pre-set values. The stimulation terminates after 15 seconds if no alteration of the Pacer Intensity or Frequency occurred by pressing one of the keys. After pressing any key, the 15 seconds timing is restarted.

The stimulation can be stopped anytime before the 15 seconds are elapsed by shortly pressing the key Stimulation Start/Stop.

During pacing the frequency and the intensity can be altered.

During pacing the heart rate alarms might be used for additional patient surveillance.

Due to the risk of electrocution the conductive surfaces of the electrodes and the patient might not be touched during stimulation. After treatment the adhesive electrodes need to be removed from the patient. Ensure that conductive surfaces of the electrodes might not be touched or get in contact with conductive parts or wet surfaces and the SavePads Plus cable is not connected to the device anymore.

If, during pacing, the pacer/defibrillation cable is interrupted or removed from the device, the stimulation is ended immediately in DEMAND mode. A continuous warning signal is given and the troubleshooting information is shown in the monitor. “Pacer electrodes open” when the cause has been remedied and after a restart, the pacer again becomes active.

During pacing it is necessary to constantly monitor the patient EKG in order to ensure the effectiveness of the stimulation. Check to see whether the pacer pulse is in diastolic.

If the energy key is pressed during pacing, the pacing is interrupted and a continuous warning signal sounds to indicate that pacing was interrupted.

The pacer can be reactivated by pressing the stimulation start/stop. The energy selection is reset. If the energy selection is reset by pressing the corresponding energy key again, the alarm becomes silent. Pacing is not automatically active and must be reactivated with the stimulation start/stop key.

The Patient shall be monitored by personal during the whole pacing procedure.

11.6 Defibrillation during pacing with adhesive electrodes

If a shockable rhythm occurs during pacing, this has to be terminated immediately by defibrillation. It is possible to defibrillate via the applied Pacer- / defibrillation electrodes.

Press the required energy key. A permanent warning signal will be emitted, since the stimulation was terminated by the energy selection.

Press the charge key in the operating panel to charge the defibrillation energy. Activate the defibrillation via the adhesive electrodes by activating the trigger key on the control panel.

To reactivate the Pacer after a successful defibrillation, the Pacer needs to be switched on again.

It is possible to defibrillate with the paddles despite attached adhesive electrodes. Charge the required energy by briefly pressing one of the Release keys at the paddles and defibrillate by simultaneously pressing both Release keys.

12 Cleaning, Servicing And Despatching

12.1 Cleaning

Clean the device only when it is switched off and the electrodes have been disconnected. For this, first remove the power module from the device or remove the plug (in case of the optional power pack) from the socket!

Do not use a dripping wet cloth for cleaning. Do not pour any liquids on the device and / or do not dip it into any liquids!

Clean the PRIMEDIC™ DefiMonitor and all accessories such as the Wall Mount Rack with any commercially available household cleaner.

Use a slightly damp and clean cloth for cleaning.

Use a standard disinfectant solution for disinfecting
(e. g. Gigasept FF)

Clean the paddles after each application. Soiling due to gel deposits can result in hazards to the user and the patient. In any case, remove the gel residue from the paddles.

12.2 Servicing

We recommend a regular inspection / servicing of PRIMEDIC™ DefiMonitor and all accessories irrespective of the frequency of use by the user / service technician at least once a year.

Check whether the casing, the cable, the SavePads and the accessories are not damaged in any way.

Check List

Check the expiry date

- the SavePads,
- AkuPak and

  replace the parts if required!

Check if

- the status display shows ‘OK’
- the device can be switched on!
- the device automatically runs the self-test after it has been switched on!
- the compartment of the power supply unit is clean!
- the device is fully equipped!
- the internal battery is older than 10 years

Hereby, pay attention to the following aspects:

- ***If any parts of the casing and/or the insulations are damaged, then get them repaired or replaced immediately.***
- ***If any parts of the casing and / or the insulations are damaged, do not operate the device or switch it off immediately!***
- ***Get the device repaired immediately from the manufacturer!***

Details on the regular safety and metrological checks according to the Medical Devices Operator Ordinance (MPBetreibV) are available in the Appendix.

12.3 Despatching PRIMEDIC™ DefiMonitor XD

If PRIMEDIC™ DefiMonitor has to be sent for upgrades or servicing, then always remove the power module from the device and send it with the device in a separate packing.

Use the original carton.

13 Disposal

The device must be sent for recycling at the end of its service life (in accordance with the local recycling regulations of each place).

In case of any doubts, detailed inquires can be made at the local recycling office.

Incorrect disposal of the device or its individual parts can result in injuries.

14 Technical Data

Defibrillation

Operating modes: asynchronous, external in Auto/Manual Mode

Synchronisation: SYNC only in Manual Mode

Impulse shape: biphasic, current controlled (CCD)

Output energy in AUTO Mode in case of:

Patient impedance	1. Step	2. Step	3. Step
25 Ohm	143 J	201 J	277 J
50 Ohm	281 J	350 J	360 J
75 Ohm	348 J	368 J	360 J
100 Ohm	344 J	343 J	343 J
125 Ohm	314 J	316 J	317 J
150 Ohm	290 J	293 J	293 J
175 Ohm	269 J	272 J	272 J

Accuracy: all figures are subject to a tolerance of +/- 15%)

Impulse length: positive Phase 11,25 ms, negative Phase 3,75 ms

Discharges: 70 discharges at 20 °C with a new fully charged accumulator

Charging time: 12 +/-3 seconds with an accumulator with 90 percent of its nominal capacity

ECG

Lead: I, II, III, aVr, aVf, Avr

Heart rate: 30 – 300 per minute

Input: Class CF, for 2-pole patient cable, defibrillation proof

Input impedance: > 5 MOhm @ 10 Hz

CMRR: > 85 dB

Input direct voltage: ± 0,5 V

Bandwidth: 0,5 – 44 Hz (- 3 dB) SR = 101 Hz

SpO_2 NELLCOR®-pulseoximetry-module:

Indication range: 100 ... 0 %

Calibration range: 100 ... 50 %

Measurement precision: SpO2

Adults 100 ... 70 % +/- 2 digits

69 ... 50 % +/- 3 digits

50 ... 0 % not specified

New-born 95 ... 70 % +/- 3 digits

For information about test procedures for the calibration ask manufacturer.

Wavelength: Red: 660 nm

Infrared: 920 nm

Light density: 0,5 lumen/cm2

Operating mode: continuous

Actualisation time: < 2 sec.

Impedance measurement

Impedance range:	0 ... 240 Ohm
Measure frequency:	30 kHz

Alarms

System:	ECG, $SpO_{2,}$, defibrillator, power supply, data storage
Physiological:	Ventricular fibrillation (VF), pulseless ventricular tachycardia (VT)
Duration of Analysis:	max. 12 seconds till the detection of VF / VT with an accumulator or battery with 90 percent of its nominal capacity
Analysedauer:	ca. 12 s bis zum Erkennen von VF / VT

Monitor

Monitor Type:	High-resolution LCD monitor, blue mode
Monitor Size:	115 x 86 mm (Diagonal 144 mm, 5.7")
Resolution:	320 x 240 Pixel (pixel size 0.36 x 0.36 mm)
Displays:	Heart rate, number of defibrillations, number of detected VF / VT, duration of resuscitation, date, time, accumulator capacity

Power Supply

AkuPak:	NiCd, 12 V / 1,4 Ah
Integrated :	100 ... 240 Volt, 50 / 60 Hz

Data Storage

Memory type:	CompactFlashCard (Industrial grade) 16 – 64 MB possible

Safety

Classification:	Safety Class I, Type CF, Defi-proof, medical device of Class IIb
Designation:	CE 0123 The device is a medical device and meets the EU Directive 93 / 42 / EEC

Miscellaneous

Operating conditions:	0°... 55° C, 30... 95 % rel. humidity, but without condensation 500 hPa ... 1060 hPa continuous operation
Storage conditions:	- 20 ... 70 °C, 20 ... 95 % rel. humidity, but without condensation, 500 hPa ... 1060 hPa ...
Dimensions:	33 x 17 x 28 cm (width x depth x height)
Weight	approx. 4,5 kg (without power supply)

Used Norms

- IEC 60601-1:1988 + A1:1991 + A2:1995
- IEC 601-2-4:2002
- IEC 60101-1-2:2001
- RTCA / DO-160D: 1997
- EN1789

Right to make changes reserved.

15 Accessory list

- Paddle Set
- SavePads
- AkuPak

Further accessory, see separate Accessory- / Price list .

16 Warranty Conditions

As the manufacturer, METRAX offers a two-year guarantee on this device from the date of purchase. Please keep your invoice as a proof of purchase. METRAX will repair or replace the device free of cost within two years of the purchase if it is found to be defective in material or manufacturing. Repairs or replacement will be at METRAX's sole discretion.

Any repairs or replacements under guarantee do not extend the original guarantee period.

Guarantee claims and any legal claims based on defects do not arise due to any minor impairment of usability, natural wear (i.e. wearing parts such as AkuPak) and tear or damages due to passing of the risk owing to improper or negligent handling, excessive strain or extraordinary outside influences not provided for under the contract. This also applies to any improper modifications or repairs carried out by the buyer or any other person.

Any other claims against METRAX will be excluded unless the claims are based on malicious intent or gross negligence or mandatory liability rules.

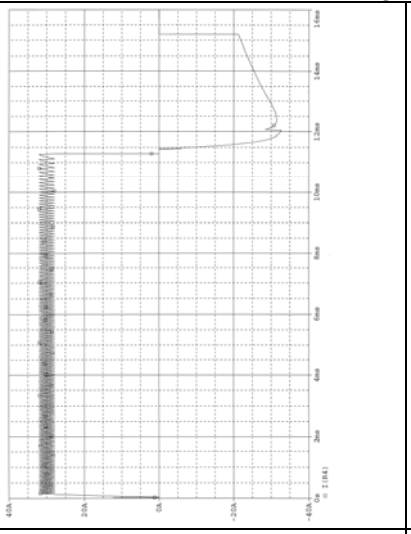
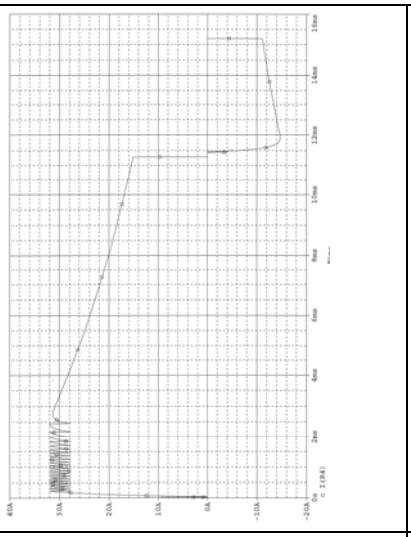
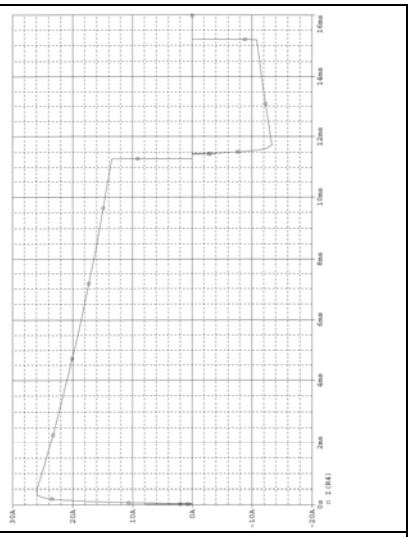
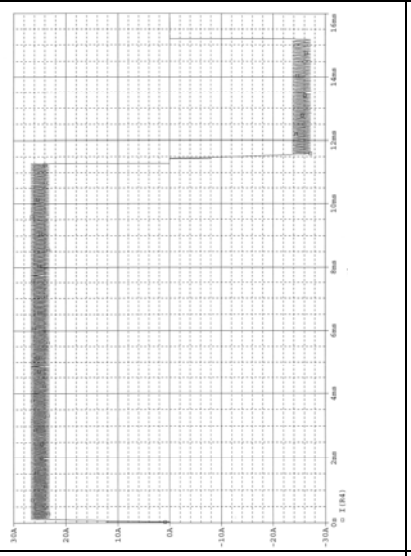
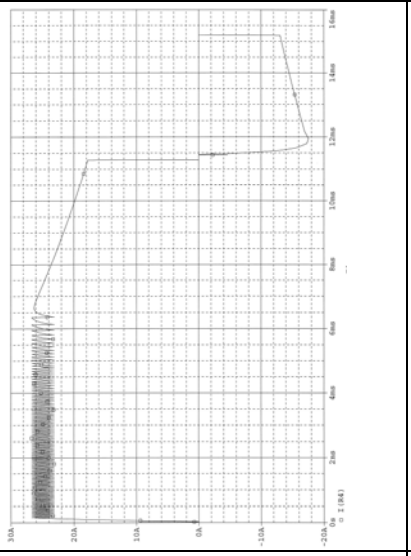
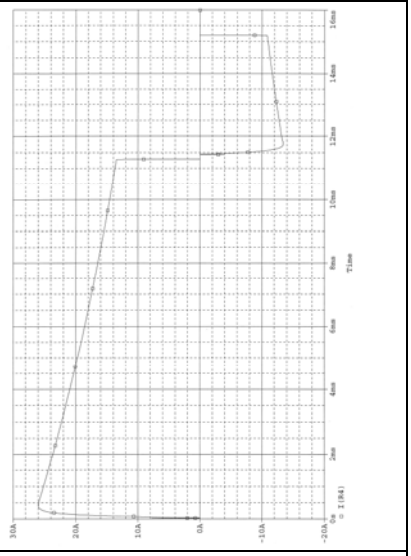
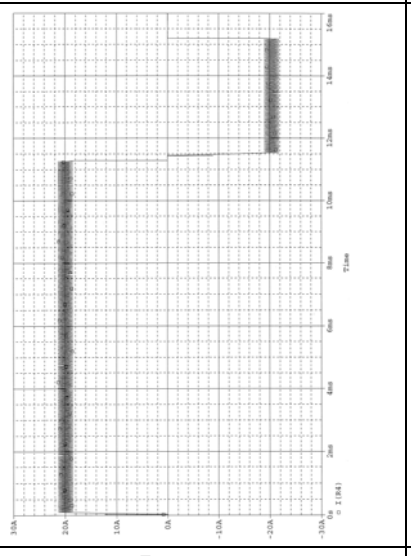
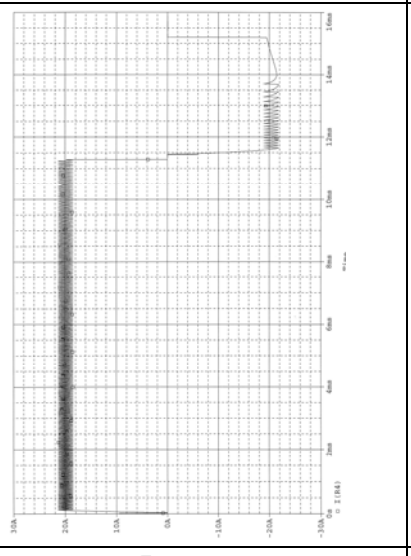
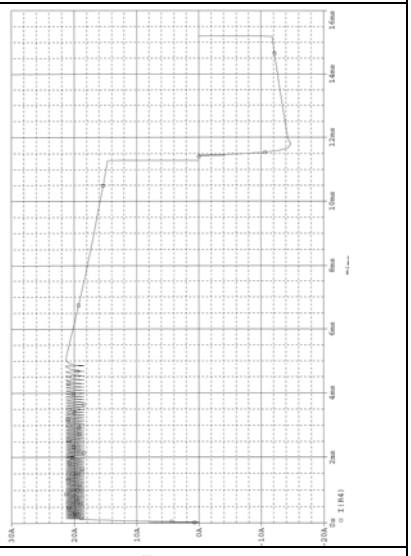
All claims of the buyer against the seller (dealer) based on defects are not affected by this guarantee.

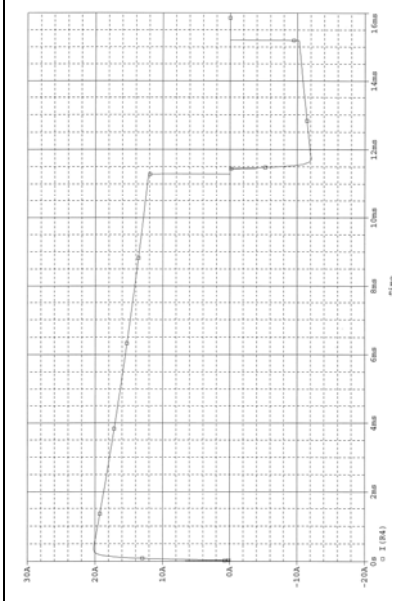
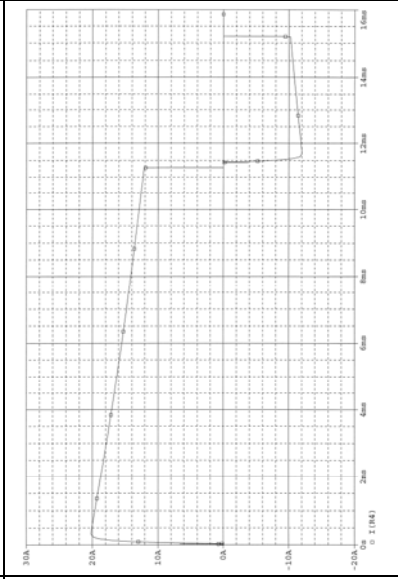
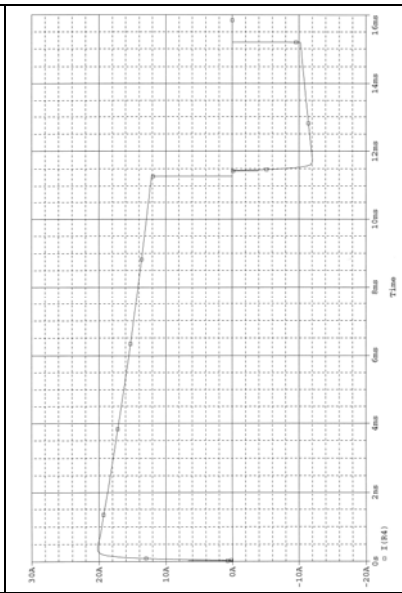
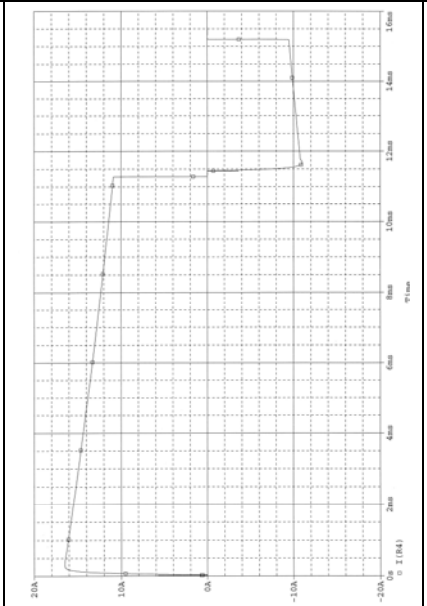
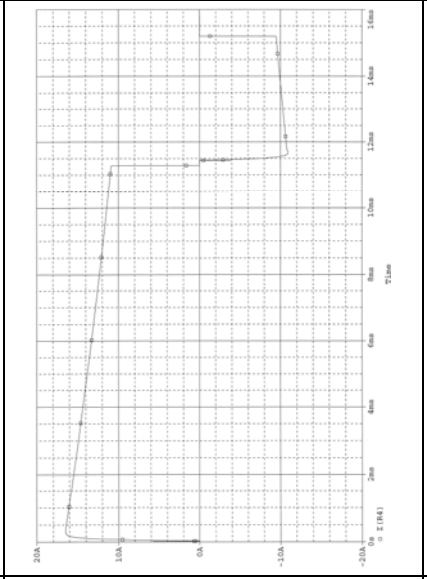
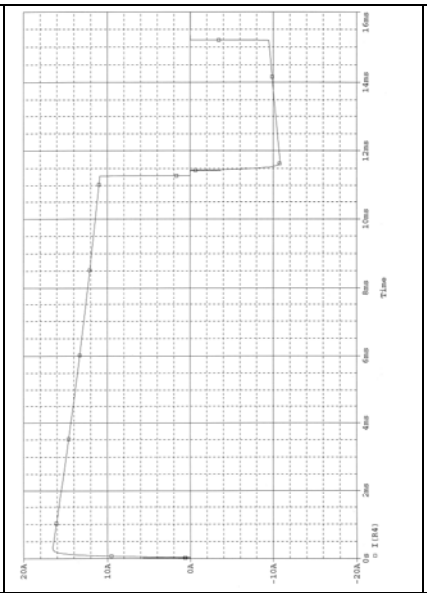
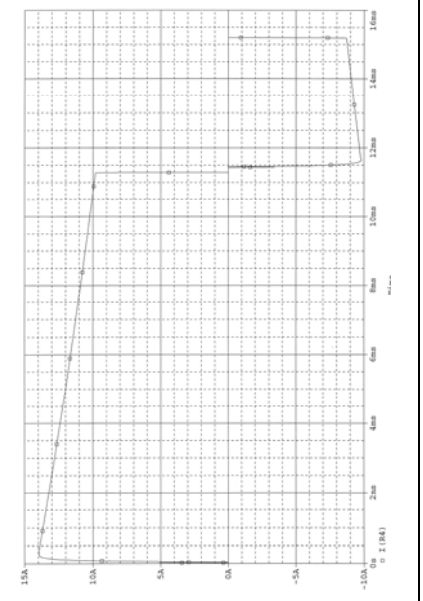
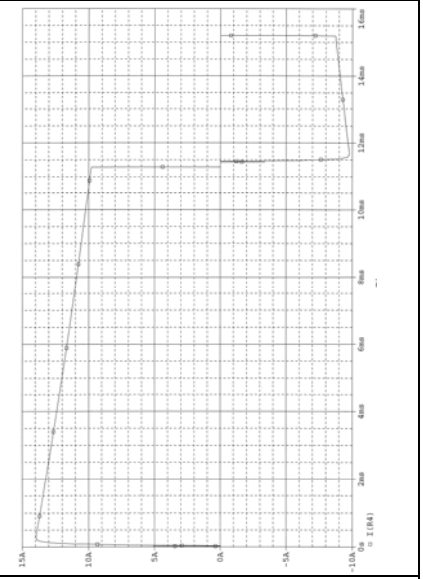
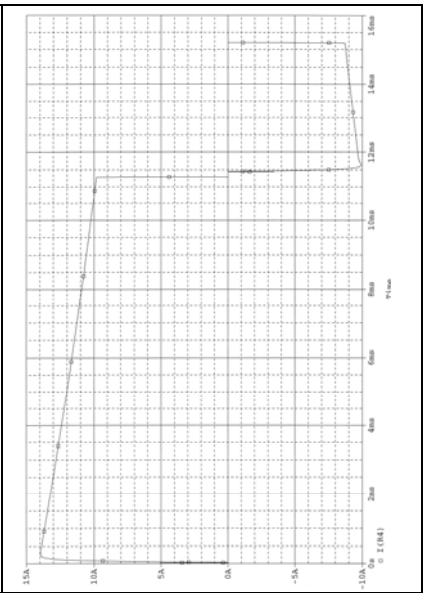
To avail guarantee, send the device along with a proof of purchase (e.g. the invoice) and your name and address to your dealer or to METRAX.

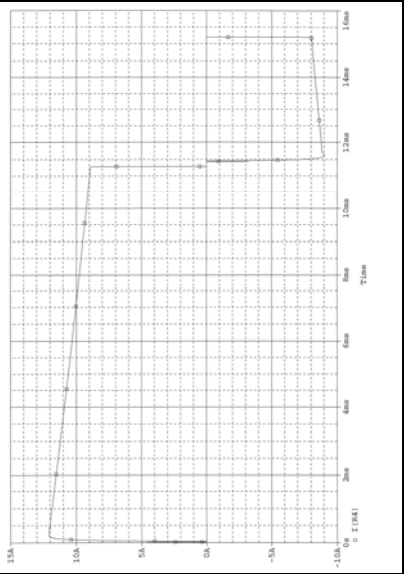
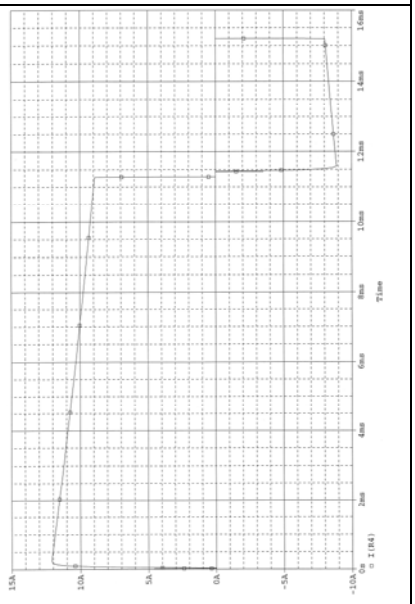
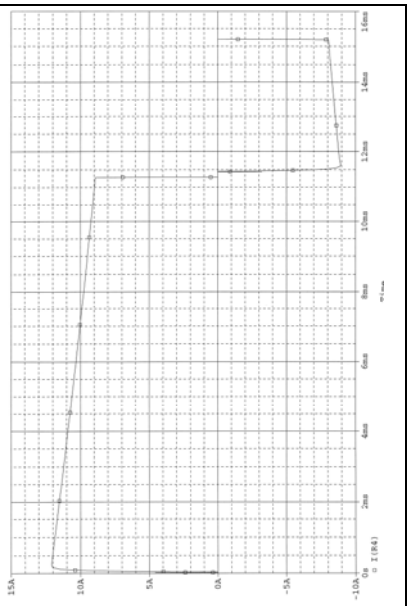
The METRAX customer service is at your service even after the guarantee period!

A1 Representation of the Current-Time Function

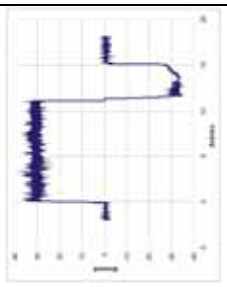
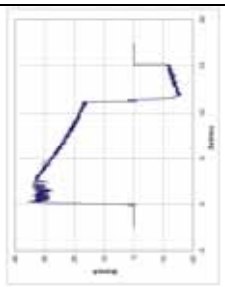
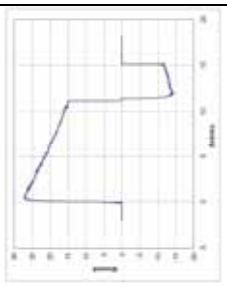
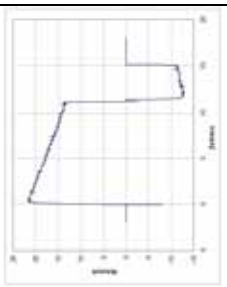
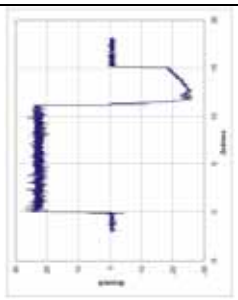
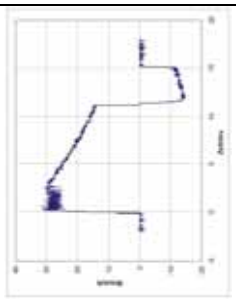
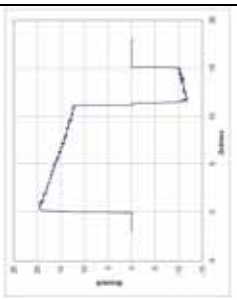
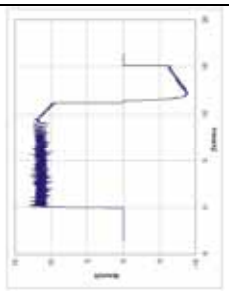
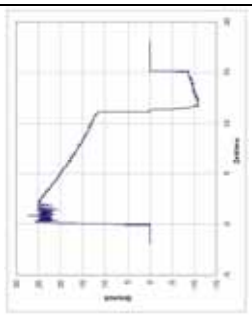
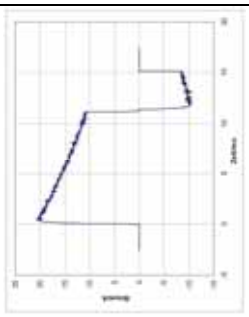
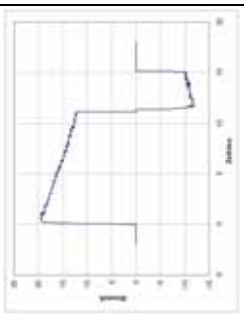
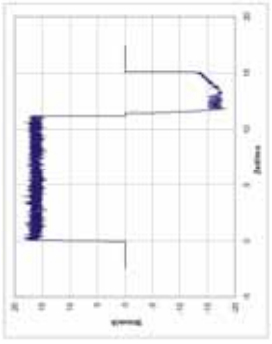
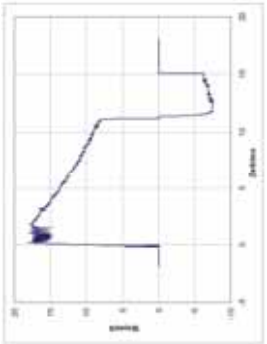
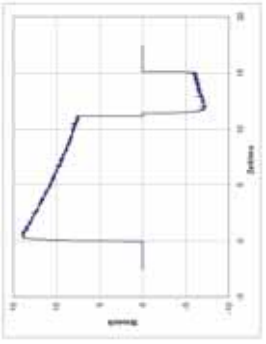
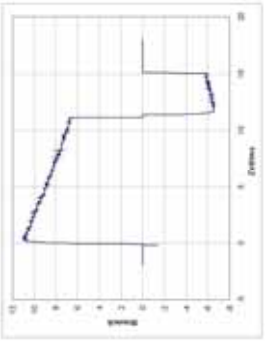
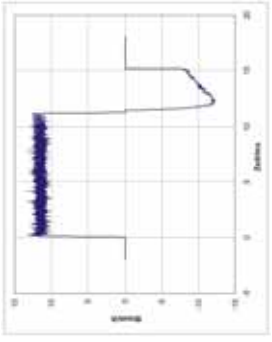
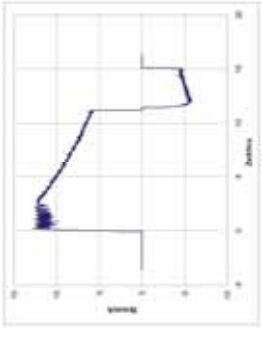
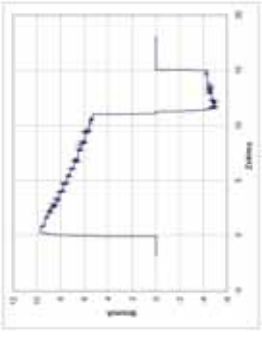
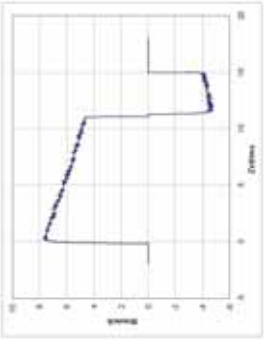
The following diagrams show the defibrillation pulses in Auto Mode in relation to the terminating resistance in wave form.

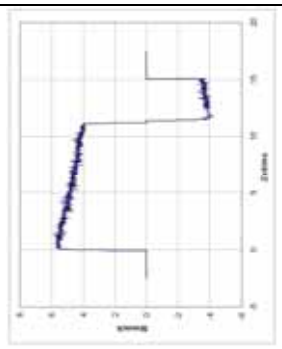
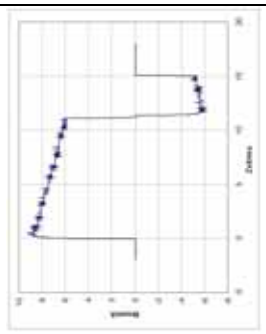
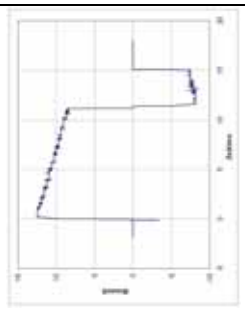
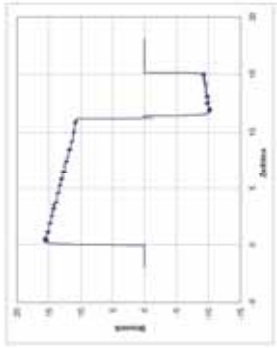
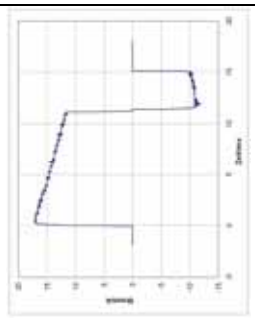
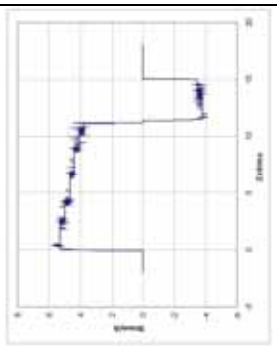
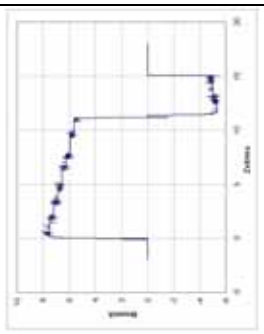
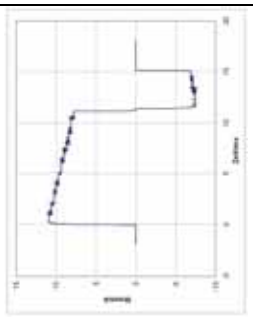
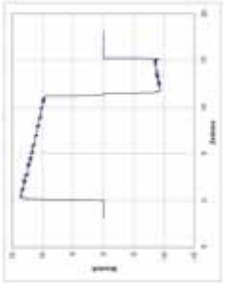
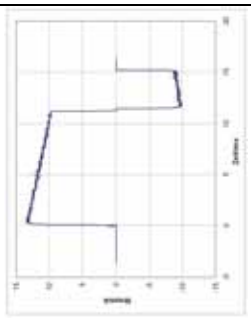
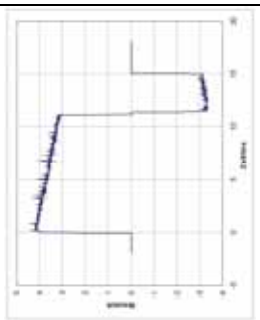
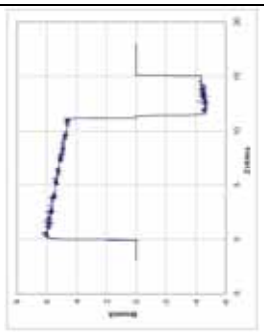
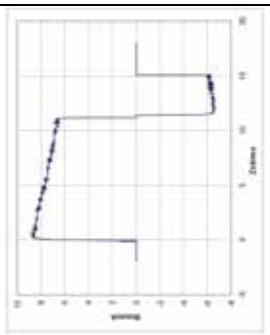
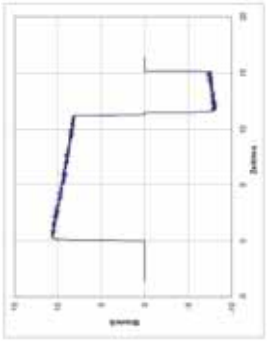
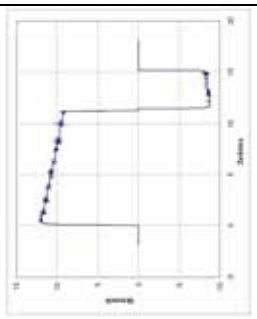
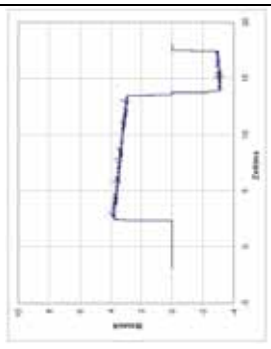
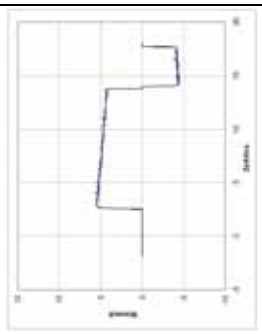
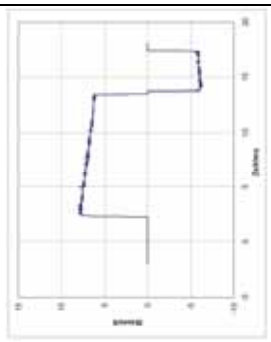
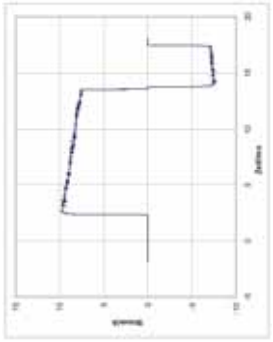
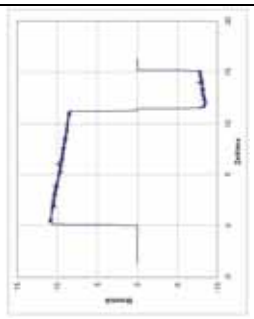
	25 Ohm	50 Ohm	75 Ohm
Step 3			
Step 2			
Step 1			

	Step 1	Step 2	Step 3
100 Ohm			
125 Ohm			
150 Ohm			

	Step 1	Step 2	Step 3
175 Ohm			

The following shows the defibrillation impulse waveforms in Manual Mode in relation to the terminating resistance in wave form.

	25 Ohm	50 Ohm	75 Ohm	100 Ohm
360 Joule				
300 Joule				
200 Joule				
100 Joule				
50 Joule				

	50 Joule	100 Joule	200 Joule	300 Joule	360 Joule
125 Ohm					
150 Ohm					
175 Ohm					
200 Ohm					

A2 System of Rhythm Detection

The rhythm detection system of the DefiMonitor analyses the ECG of the patient and informs you if the DefiMonitor has detected a shockable rhythm and vice versa.

This system enables a person not trained in the analysis of ECG rhythms to use defibrillation measures for victims of ventricular fibrillation, pulseless ventricular tachycardia.

The rhythm detection system of the device:

- Detects the electrode contact

- Analyses the ECG automatically

- Guides the operator during the defibrillation shock therapy

The transthoracic impendence of the patient is measured by the defibrillation electrodes. If the base line impedance is higher than the maximum limiting value, the device determines if the electrodes do not have adequate contact with the patient or have not been connected to the device properly. The ECG analysis and the delivery of defibrillation shocks are therefore stopped. The voice prompt instructs the user to 'Check electrodes', if the contact of electrodes is not sufficient.

Automatic Interpretation of the ECG

The rhythm detection system of the device was so designed that a defibrillation shock is recommended if the system was connected to a patient who is unconscious, not breathing, does not have a pulse and the system detects:

Ventricular fibrillation – if the peak to peak amplitude is higher than the asystole threshold value (0.2 mV nominal)

Ventricular tachycardia

For all other ECG rhythms that do not meet these criteria, including asystole and normal sinus rhythms, the rhythm detection system of the device does not recommend defibrillation.

ECG analysis is carried out on a sample ECG of at least seven seconds.

Operator Control to Deliver Defibrillation Shocks

The rhythm detection system of the device charges the energy automatically if the device detects a shockable rhythm. Optical and voice messages are generated to indicate that the device is recommending a defibrillation shock. If a defibrillation shock is recommended, decide if the shock should be delivered and when it should be delivered.

The algorithm:

- observes the ECG rhythm over a continuous history of ten seconds, of which seven seconds are used for the first diagnosis or to display the message 'Shock Recommended'.
- Measuring the symmetry and energy content of the signal
- Filtering and measuring artefacts and sounds
- Detecting pacemakers
- Measuring the QRS rate and width

Cardiac rhythms used to test the rhythm detection system of the device

Rhythm Class	Specifications
Shockable rhythm – VF	DefiMonitor fulfils the AAMI DF 39 requirements and the AHA recommendation for the sensitivity > 90 %
Shockable rhythm – VT	DefiMonitor fulfils the AAMI DF 39 requirements and the AHA recommendation for the sensitivity > 75 %
Rhythm not shockable – normal sinus rhythms	DefiMonitor fulfils the AAMI DF 39 requirements for the specificity > 95 % and the AHA recommendation for the sensitivity > 99 %
Rhythm not shockable - asystole	DefiMonitor fulfils the AAMI DF 39 requirements and the AHA recommendation for the sensitivity > 95 %

Databases used for validation: AHA, MIT and CUDB

$$Sensitivity = \frac{\text{Number of "correct shockable" algorithm decisions}}{\text{Total number of EKGs, for which a pulse is clinically recommended}}$$

$$Specificity = \frac{\text{Number of "correct non-shockable" alogrithm decisions}}{\text{Total number of EKGs, for which a pulse is not clinically recommended}}$$

A3 General instructions for the use of pulsoximeters

What is pulsoximetry?

A pulsoximeter determines the SpO2 value (oxygen saturation) by optical measuring methods. This method is based on the penetration of light of different wavelengths through tissues and vessel.

The components of blood important for the SpO2 measuring, are oxygenated (oxygen-enriched) or deoxygenated (without oxygen) haemoglobin, i.e. exactly the components necessary for oxygen supply of the organism.

The tissues and vessels are "penetrated by light" with the help of transmitter-receiver elements. Depending upon the oxygen saturation of the blood the quantity of light arriving on the receiver side of the transmitter changes. Thanks to the application of precise modules and calibrated sensores, highly exact SpO2 measures are possible.

Usual measure points for the sensors are

- Finger Tips
- Toes
- Earlobes
- heels

Why are there different sensors?

As described in, among others, chapter 6.2 (selection of the correct SpO2 sensor) different sensors have to be used for different patients to guarantee reliable and exact measures.

The following factors have to be taken into account:

- weight of the patient
- activity of the patient
- duration of the measure
- blood circulation in the limbs
- possible measuring point
- physical condition of the patient
- sterile measure necessary?

Evidently no single sensor can meet all the, to some extent contradictory, requirements. The different SpO2 sensors are designed for specific purposes.

As an example may serve the sensor DS-100 A or the D-YS respectively from NELLCOR®. DS-100 A allows rapid handling and it is simple to be slipped on fingers of different thickness thanks to its sophisticated mechanism. But it is not suitable for children because of its geometry. Using this sensor for patients who move a lot is also not possible, as, due to the design of the casing the sensor might slip off the patients finger. As the D-SY has no casing this sensor D-SY may be applied for higher weight classes, moreover it might be positioned with more flexibility and can fixed with an adherent strip, which reduces the rapid positioning of this sensor.

As the measuring of the oxygen saturation is an optical method, the following influencing factors might affect the results:

- direct sun light
- strong artificial light (e.g. operating room lighting)
- infrared lamps
- ultraviolet lamps (bilirubin lamps)

The influence of the above mentioned factors can be reduced positioning the sensor correctly and using covers of the sensors.

More influencing factors are:

- dirty measuring point
- incorrect cleaning of the sensor
- opaqueness or colour distortion at the measuring point e.g. by nail-varnish
- highly active patient
- injected contrast media, (e.g. indiocyanide green or methylene blue)
- high proportions of dysfunctional haemoglobin (carboxy haemoglobin)
- wrong point of positioning (e.g. point with venous pulse)
- use of the pulsoximeter close to strong source of energy like e.g. nuclear spin tomography
- sensor applied too rigidly
- arterial occlusion close to the sensor
- blood congestion e.g. by artery catheter or by sphygmomanometer

Some of these factors are easy to recognize (e.g. nail-varnish) and are removable; a repeatable result can be obtained at a different measuring point.

Other factors (e.g. contrast media or blood serum disorder) are not as easy to be determined.

The SpO2 measure should not be the only method applied to monitor the vital functions due to this multitude of influencing factors. More parameters must always be monitored (e.g. ECG, blood pressure, respiration ...).

The SpO2 measure can be an important instrument for the diagnosis of patients, when the sensor is used correctly, the specific warnings and hints on the use of the sensor are observed and the clinical symptoms are taken into consideration.

A4 Guidelines And Manufacturer's Statement – Electromagnetic Emissions –

The PRIMEDIC™ DefiMonitor is intended for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
FR emissions CISPR 11	Group 1	The PRIMEDIC™ DefiMonitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
FR emissions CISPR 11	Group 2	The PRIMEDIC™ DefiMonitor must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
FR emissions CISPR 11	Class [A or B]	
Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or not applicable]	
Voltage fluctuations / flicker emissions IEC 61000-3-3	[Complies or Not applicable]	
	[See 6.8.3.201 a) 3) and Figure 201]	The PRIMEDIC™ DefiMonitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
	[See 6.8.3.201 a)3) and Figure 201]	The PRIMEDIC™ DefiMonitor is suitable for use in all establishments other than domestic and those directly connected to the public-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 14 – 1	Complies	The PRIMEDIC™ DefiMonitor is not suitable for interconnection with other equipment.
RF emissions CISPR 15 HF-Aussendungen nach CISPR 14-1	Complies	The PRIMEDIC™ DefiMonitor is not suitable for interconnection with other equipment.

The PRIMEDIC™ DefiMonitor is intended for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

The PRIMEDIC™ DefiMonitor is intended for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	[V_1] V	$d = [\frac{3,5}{V_1}]\sqrt{P}$
	10 Vms 150 kHz to 80 MHz in ISM bands[a]	[V_2] V	$d = [\frac{12}{V_2}]\sqrt{P}$
Conducted RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	[E_1] V/m	$d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40,66MHz to 40,70 MHz.

[b] The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM].

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

The PRIMEDIC™ DefiMonitor is intended for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V_{eff} 80 MHz to 2,5 GHz	[V_1] V [E_1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PRIMEDIC™ DefiMonitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer´s declaration – electromagnetic immunity			
The PRIMEDIC™ DefiMonitor is intended for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment.			
Immunity	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[V_1] V [E_1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PRIMEDIC™ DefiMonitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM]. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the PRIMEDIC™ DefiMonitor

The PRIMEDIC™ DefiMonitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PRIMEDIC™ DefiMonitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PRIMEDIC™ DefiMonitor as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter M**			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0,01				
0,1				
1				
10				
100				

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz: 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and the PRIMEDIC™ DefiMonitor

The PRIMEDIC™ DefiMonitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PRIMEDIC™ DefiMonitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PRIMEDIC™ DefiMonitor as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01			
0,1			
1			
10			
100			

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer´s declaration – electromagnetic immunity			
The PRIMEDIC™ DefiMonitor is suitable for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment.			
Immunity	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a] 10 V/m 80 MHz to 2,5 GHz		The PRIMEDIC™ DefiMonitor must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of [shielding effectiveness / filter attenuation specification]. See [appropriate section of ACCOMPANYING DOCUMENTS]. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than [field strength] V/m.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 2 It is essential that the actual shielding effectiveness and filter attenuation of shielded location be verified to assure that they meet the minimum specification.			
[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz: 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. [b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the PRIMEDIC™ DefiMonitor is used exceeds [field strength] V/m, observe the PRIMEDIC™ DefiMonitor to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the PRIMEDIC™ DefiMonitor or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

Guidance and manufacturer´s declaration – electromagnetic immunity			
The PRIMEDIC™ DefiMonitor is suitable for use in the electromagnetic environment specified below. The customer or the user of the PRIMEDIC™ DefiMonitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz		The PRIMEDIC™ DefiMonitor must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of [shielding effectiveness / filter attenuation specification]. See [appropriate section of ACCOMPANYING DOCUMENTS]. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than [field strength] V/m.[a] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 2 It is essential that the actual shielding effectiveness and filter attenuation of shielded location be verified to assure that they meet the minimum specification.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the PRIMEDIC™ DefiMonitor is used exceeds [field strength] V/m, the PRIMEDIC™ DefiMonitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the PRIMEDIC™ DefiMonitor or using a shielded location with a higher RF shielding effectiveness and filter attenuation.			

A5 General Instructions And Rules For Using The Optional AkuPak

A nickel cadmium accumulator (NiCd accumulator) has been selected for the operation of PRIMEDIC™ DefiMonitor because in practice, this type of an accumulator has more advantages compared to other types.

The NiCd accumulator has a higher energy density, that is, the PRIMEDIC™ AkuPak of the same size is able to give a considerably higher number of defibrillations and / or has a longer operational ability than, for example, a comparable lead accumulator.

Using a NiCd accumulator is next to unproblematic. Due to a modern, microprocessor controlled charging connection, like the one used in the PRIMEDIC™ AkuPak, the charging time required is very short and the life of the battery can also be prolonged.

If the NiCd accumulator is recharged without discharging it fully over a long period of time, a typical phenomenon called the 'Memory Effect' occurs. Owing to the 'Memory Effect', inspite of having an ostensibly large capacity, the accumulator functions as if it were a smaller accumulator with a smaller capacity.

An example for clarification

An accumulator has a capacity of approx. 60 defibrillations. The device is used for five defibrillations, after which the accumulator is charged again. If this method of operation continues over a long period of time, the 'memory effect' can set in. It means that the capacity of the accumulator has reduced to five or six defibrillations because the accumulator was 'trained' for five defibrillations'.

Reversing the 'Memory Effect' can be very expensive. So, the accumulator cannot be used properly if its 'residual capacity' remains below a practicable value.

Preventing the 'Memory Effect'

In order to prevent the 'Memory Effect', the accumulator must be discharged fully from time to time, so that in the meantime, a complete charging cycle can be carried out. In practice, this can be done in a number of ways:

- Do not recharge the accumulator immediately if it was discharged only fractionally. Most of the times, there is still enough energy to continue using the device with the remaining energy at a later time. The PRIMEDIC™ AkuPak does not always recharge an accumulator immediately. The accumulator is charged only after a certain threshold value has been crossed.
- Before recharging the accumulator, the remaining capacity should be used up, for example, through several defibrillations. This is not required each time the accumulator is charged, but only from time to time (weekly or monthly, depending upon how often it is used).
- The optimal care for an accumulator is a fully automatic charging and discharging device, whereby a specific amount of discharging takes place each time the accumulator is charged. For reasons of safety, this method of charging is not used in case of accumulators that are loaded in the defibrillator directly. Otherwise, this can lead to an unfavourable scenario where the defibrillator is required at just the time when the accumulator has been completely discharged.

The fully-automatic discharge / charge device is realised as a care function in the charge console of the PRIMEDIC DefiMonitor. A second PRIMEDIC™ battery pack can be charged with this option (can also be retrofitted) with which the "memory" effect can be effectively avoided with the care function.

Other Effects of Accumulators

Accumulators have two other features in the daily operation:

- Self-discharge
- Aging after longer use

In practical application, the self-discharge of an accumulator means that a full accumulator loses it charge slowly but steadily. After about four weeks, only 90 percent of the capacity is available. Generally, this effect needs to be considered, only if several accumulators were charged as 'reserves'.

PRIMEDIC™ AkuPak observes this self-discharge effect and balances it with a charge conservation circuit.

Even with optimum care, after a unpredictable period (depending on the frequency of use), an **aging effect** is seen in accumulators. After several hundreds of charging cycles (depending on the type), an accumulator can no longer transfer the absorbed electrical energy to the chemical storage component. As a result, the accumulator can no longer be used and must be replaced by a new one.

A6 Recommended Safety Checks

According to the Medical Devices Operator Ordinance (MPBetreibV) § 6 (Safety Checks), the user is required to undertake regular checks. By the Medical Devices Operator Ordinance (MPBetreibV) § 6, METRAX prescribes these checks every 24 months in the FRG, this is only recommended in other countries.

These safety checks must be assigned to only those persons, who by virtue of their training, their knowledge and their experience gained from practice, can carry out these checks correctly and independently.

If the safety-related checks show any defects that can harm the patients, operators or any other person, then according to the Medical Devices Operator Ordinance (MPBetreibV) § 3, the person carrying on the checks must inform the relevant authorities immediately.

The following information must be entered in the medical device book required to maintained under the Medical Devices Operator Ordinance (MPBetreibV) § 7:

- time of the tasks
- name of the person and / or company carrying out the tasks and
- the measures carried out.

METRAX is responsible for the data given in the operating manual only. This applies especially to any new settings, repairs and changes to the device.

During the regular checks, the service technician must carry out the following tasks and tests:

1. Check the device for any external damage
   - Is the casing intact?
   - Are the SavePads intact? Check the expiry date!
   - Are the SavePads – Input socket and contact plugs intact?
   - Is the type plate on the rear of the device and the back side of the power supply unit readable?
2. Examine the device for any damaged operating elements.
   - Is the key pad readable and intact?
   - Are the buttons intact and functioning?
3. A check of the electrical fuse must occur under operating conditions. A measure of the deviated and patient auxiliary currents corresponding to IEC 601-1. Select the standard deviation and measurements for the CF type.
4. Check the display elements
   - Are all the LEDs active for about two seconds after the defibrillator is switched on?
   - Does the warning buzzer sound for about two seconds after the defibrillator is switched on?
5. Measure the charging time
6. Measure the output

   While checking the defibrillation energy, a deviation of ± 15 % at 50 Ω is allowed.
7. Function of the ECG monitor.
   - Are all the parameters displayed in the monitor?

   Feed an ECG signal with known frequency from an ECG simulator (Defi-Tester) through a service cable.

– Is the heart rate displayed with a tolerance of ± 10 %?

– Is the Sync signal in Manual mode placed to the corresponding R-peaks ?

8. Function of the accumulator / charging circuit

Charging indicator on the front panel lights up after the AkuPak in the defibrillator is connected.

9. Function of Pulsoximetery (*)

Plug in NELLCOR Sensor DS-100 A and the SpO_2 Adapter cable. To control the function put index finger into the sensor or connect a SpO_2 test advice to the SpO_2 patient cable.

Is the SpO_2 value displayed ?

Is the Pulse curve displayed ?

(*) =only valid, if the corresponding function is integrated into the device. The Pulseoximetry is only integrated in model **DefiMonitor XD3, XD30, XD300 and XD330**.